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1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

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4 W. NORMAN SCOTT AND GILES R. ) Civil Action  
5 SCUDERI, )  
6 Plaintiffs, )  
7 v. )  
8 ZIMMER, INC. AND ZIMMER )  
9 TECHNOLOGY, INC., )  
Defendants. ) No. 10-772-GMS

10 - - -

11 Wilmington, Delaware  
12 Tuesday, June 26, 2012  
13 9:00 p.m.  
14 Day 2 of Trial  
15 - - -

16 BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

17 APPEARANCES:

18 KAREN JACOBS LOUDEN, ESQ.  
19 Morris, Nichols, Arsht & Tunnell, LLP

20 -and-

21 JACOB W. BUCHDAHL, ESQ.,  
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25 -and-

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1       **APPEARANCES CONTINUED:**

2               **FREDERICK R. COTTRELL, III, ESQ.**  
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5               **BRYAN S. HALES, P.C., and**  
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10                              -   -   -

:03:16 1 THE COURT: Good morning.

:03:17 2 (Counsel respond "Good morning.")

:03:20 3 THE COURT: Let's resume. Dr. Rohr.

:03:23 4 (... WILLIAM L. ROHR, having been previously  
:03:27 5 sworn as a witness, was examined and testified further as  
:03:35 6 follows ...

:03:49 7 THE COURT: Mr. Cottrell.

:03:50 8 MR. COTTRELL: Good morning, Your Honor.

:03:51 9 Your Honor, a quick housekeeping matter before I  
:03:54 10 resume. I will just be brief.

:03:57 11 We understand the Court's ruling at the pretrial  
:04:00 12 that all documents are in for possible use at trial subject  
:04:04 13 to any renewed objections. And there haven't been any  
:04:08 14 objections to Dr. Rohr's exhibits by either side. So we  
:04:11 15 haven't been formally moving their admission.

:04:15 16 THE COURT: There is no need to do so.

:04:16 17 MR. COTTRELL: At the end we will get together  
:04:18 18 and make sure we provide the Court with the documents  
:04:21 19 actually used during trial with the proper lists.

:04:24 20 THE COURT: I won't need them at the end. I  
:04:26 21 will need them at the time of briefing, is when I will need  
:04:29 22 them.

:04:30 23 MR. COTTRELL: We were just trying to speed  
:04:32 24 things up, Your Honor.

:04:33 25 THE COURT: That is final. We will see what

Rohr - cross

1 happens, as things move along, how I feel, what my comfort  
2 level is with regard to what I am listening to, as to what I  
3 do you with regard to the verdict. We will just see.

4 If it gets to the point that you are going to  
5 need to write, you will need to write, I will reasonably put  
6 you on an expedited briefing schedule.

7 MR. COTTRELL: Thank you, Your Honor. May I  
8 proceed?

9 THE COURT: Yes.

10 CROSS-EXAMINATION CONTINUED.

11 BY MR. COTTRELL:

12 Q. Good morning, Dr. Rohr.

13 A. Good morning.

14 Q. Let me -- I let you and the Court know that I was  
15 about to move on to a different topic yesterday. So I would  
16 like to do that.

17 It is the concept of the cam-spine interaction  
18 in the replacement knee. Are you familiar with that?

19 A. Yes.

20 Q. And I am going to ask you a few questions about the  
21 cam-spine interaction. I am sure we will hear more about it  
22 later in the trial. Is it not correct that you believed  
23 implants prior to the PS or the LPS had the cam-spine  
24 interaction wrong because the instant center rotated up the  
25 cam instead of down the cam as flex increased?

Rohr - cross

:05:46 1 A. That's correct.

:05:47 2 Q. And yesterday you mentioned a fellow named Todd

:05:51 3 Johnson at Zimmer. Correct?

:05:52 4 A. Correct.

:05:52 5 Q. He was an engineer?

:05:54 6 A. Yes.

:05:54 7 Q. And he was involved with the cam-spine interaction?

:05:59 8 A. Yes.

:05:59 9 Q. And at some point when you were at Zimmer you tasked

:06:05 10 him to figure out how to solve the problem with the cam

:06:09 11 moving up the spine instead of down as flex increased.

:06:12 12 Correct?

:06:12 13 A. Yes. He was to change the direction of the cam from

:06:14 14 up to down.

:06:15 15 Q. And the solving of that problem was the result of Todd

:06:23 16 Johnson's work as you directed him?

:06:25 17 A. Yes.

:06:26 18 Q. Now, I believe you may have answered this yesterday,

:06:31 19 so I apologize. Much of the discussion around design for

:06:36 20 the LPS Flex occurred after you left Zimmer. Correct?

:06:40 21 A. Yes.

:06:40 22 Q. But the concept for the cam-spine interaction which we

:06:46 23 have just discussed would have been adopted with whatever

:06:49 24 modification was necessary to incorporate deeper flex?

:06:54 25 A. It was actually incorporated in the Legacy design.

Rohr - cross

:06:57 1 Q. In the Legacy design.

:06:58 2 So the modifications of the cam-spine

:07:04 3 interaction problem, I think you stated, would have been an

:07:07 4 engineering problem at that point?

:07:11 5 A. That's one of the aspects, yes.

:07:13 6 Q. Doctor, let me ask you a couple of questions about --

:07:35 7 Mr. Smith, if we can have DTX-5 brought up, the '786 patent

:07:40 8 brought up.

:07:41 9 Doctor, I think you saw this patent yesterday.

:07:52 10 It should be in your book?

:07:53 11 A. Yes. The '786.

:07:55 12 Q. You are a named inventor on it?

:07:57 13 A. Yes.

:07:57 14 Q. Now, is it not correct that you don't recall who came

:08:01 15 up with the idea of using a module to thicken posterior

:08:06 16 condyles to increase flexion?

:08:11 17 A. What I said was it had come up several times. Who had

:08:15 18 actually originally proposed it, I don't know. But we had

:08:18 19 discussed it at length.

:08:19 20 Q. You had discussed it at length but you don't know who

:08:22 21 originally proposed it?

:08:23 22 A. That's correct.

:08:27 23 Q. You don't remember, for example, Dr. Scott coming up

:08:30 24 with the idea?

:08:31 25 A. Again, as I tried to explain yesterday, these were

Rohr - cross

:08:34 1 sessions where everybody was inputting their information.  
:08:38 2 It was hard at any one time in the middle of this to tell  
:08:40 3 you who actually came with which specific idea in those  
:08:47 4 sessions.

:08:47 5 Q. But there wasn't, for example, a drawing from Dr.  
:08:50 6 Scott on the module that you recall?

:08:53 7 A. That I recall here today, no.

:08:54 8 Q. Let me ask you a few questions, Doctor, if I could,  
:09:01 9 about Dr. Scuderi. We have talked about both Dr. Scott and  
:09:05 10 Scuderi yesterday. Let me ask you a couple of questions  
:09:08 11 about Dr. Scuderi.

:09:10 12 Is it fair to say you worked with Dr. Insall a  
:09:15 13 fair bit when you were at Zimmer?

:09:16 14 A. Yes.

:09:17 15 Q. And you worked with Dr. Scott perhaps less so but  
:09:21 16 still you worked with him while you were at Zimmer?

:09:24 17 A. I would say about the same amount as with John Insall.

:09:27 18 Q. But Dr. Scuderi, is it fair to say, you worked with  
:09:30 19 perhaps less than the other two?

:09:34 20 A. Time-wise? It's hard to typify. I worked with Dr.  
:09:38 21 Scuderi as much in surgery. But in other aspects, it's an  
:09:42 22 issue of seniority. There were meetings that I had with  
:09:45 23 John Insall and Norm Scott. At Gil Scuderi's level of  
:09:51 24 involvement at that time, he just wasn't a part of those  
:09:53 25 meetings. On a time basis, certainly I spent more time with

Rohr - cross

:09:57 1 Dr. Scott and Dr. Insall.

:09:58 2 Q. Is it not true that you have no recollection of Dr.  
:10:01 3 Scuderi being involved in the thickening of the posterior  
:10:05 4 condyles?

:10:05 5 A. I don't remember that, no.

:10:06 6 Q. And you have no recollection of Dr. Scuderi being  
:10:13 7 involved in the discussion of the module that we were just  
:10:17 8 talking about?

:10:18 9 A. He may have been in one of those discussions. Some of  
:10:20 10 those sessions where we talked about some of these extra  
:10:24 11 features, there were more people at the meetings. Again, I  
:10:27 12 can't tell you who was at any one specific meeting.

:10:30 13 Q. If you did have discussions with Dr. Scuderi about the  
:10:33 14 module, it was after the concept had been generated by  
:10:37 15 someone?

:10:38 16 A. Well, again, I did my drawing independently, long  
:10:41 17 before any of this. And as best I understand it, John  
:10:45 18 Insall, since I wasn't with him at the time he did his  
:10:48 19 drawing, did it independently of me.

:10:50 20 Q. Is it not correct that Dr. Scuderi was not involved in  
:10:59 21 what you described as the nuts and bolts of the '729 patent?

:11:06 22 A. Well, when you say not involved, he was tasked, I  
:11:09 23 know, during part of this, to do cadaver work, et cetera. I  
:11:13 24 didn't interact directly with him on that. The engineers  
:11:16 25 did on a more direct level.



Rohr - cross

1 Q. Do you recall using that term at your deposition, that  
2 he wasn't involved in the nuts and bolts of the '729?

3 A. By nuts and bolts, to me, that's one actually sitting  
4 down and hammering out this issue on '729. As I have said  
5 several times, the issue is how you go about it, whether you  
6 extend the condyle or whether you make the box smaller.  
7 That to me is the nuts and bolts. It's the heart of the  
8 concept.

9 All of these other features, how you add pieces  
10 and whether you do it with what kind of modularity and what  
11 those angles are, to me, that's not the nuts and bolts.  
12 That's just reducing this business to practice.

13 So as I have said, the only really serious  
14 discussions about this basic concept of how you increase  
15 this flexion and this issue about how you shape this  
16 posterior condyle was primarily a discussion between John  
17 Insall, Norm Scott and myself.

18 Q. And the concept is what we talked about yesterday,  
19 your drawing and Dr. Insall's drawing?

20 A. Yes. And we had discussed the concept many times  
21 among ourselves, and then the drawings were done separately  
22 at different times.

23 Q. But the drawings that you and Dr. Insall came up with  
24 were sort of the start of the whole thing?

25 A. I didn't actually -- well, we probably had discussed

Rohr - cross

:12:46 1 the concept of the Asian issue. John Insall, Norm Scott and  
:12:50 2 I had discussed it several times. And then, again, because  
:12:54 3 I don't have a calendar, I can't put together for you  
:12:57 4 exactly when my drawing was relative to those discussions,  
:13:00 5 versus when John did his drawing. No, I don't remember  
:13:02 6 those exact dates. But that was all in roughly the same  
:13:06 7 time frame.

:13:06 8 Q. Now, Doctor, if we could put up -- Mr. Smith, if we  
:13:12 9 could put up DTX-79?

:13:19 10 It's in your book, Doctor.

:13:26 11 Do you see it, Doctor?

:13:37 12 A. Yes, I do.

:13:38 13 Q. It's a memo from you to Paul -- help me on the  
:13:45 14 pronunciation there?

:13:47 15 A. Schoenle.

:13:47 16 Q. Schoenle, dated May 17, 1996. Have you seen this  
:13:54 17 document before?

:13:55 18 A. Yes.

:13:55 19 Q. And do you generally recall sending it?

:13:58 20 A. I dictated it. My secretary signed it.

:14:01 21 Q. And it fairly characterizes that you and Dr. Insall  
:14:06 22 had been discussing the idea of a mobile-bearing knee system  
:14:10 23 based on the rotating platform principal but which also  
:14:13 24 incorporated a cam mechanism. Correct?

:14:17 25 A. That's correct.

Rohr - cross

:14:23 1 Q. Doctor, yesterday you were asked some questions on  
:14:34 2 direct about, you were working with the Kirkland & Ellis  
:14:41 3 firm at one point and then weren't working with the Kirkland  
:14:45 4 & Ellis firm at one point. Do you recall that?  
:14:46 5 A. Yes, I do.  
:14:47 6 Q. You were by that time, by the time of this litigation,  
:14:53 7 you were a former Zimmer employee. You weren't employed by  
:14:57 8 them?  
:14:57 9 A. That's correct.  
:14:57 10 Q. Kirkland & Ellis represented you at your deposition in  
:15:00 11 the Delaware case. Correct?  
:15:02 12 A. That's correct.  
:15:02 13 Q. And then there was an arbitration that just happened  
:15:06 14 between, a related arbitration between the parties, but they  
:15:09 15 were not representing you at the time?  
:15:10 16 A. That's correct.  
:15:10 17 Q. And you gave testimony at the arbitration?  
:15:13 18 A. That's correct.  
:15:13 19 Q. But you weren't represented at the arbitration by  
:15:16 20 anyone?  
:15:17 21 A. That's correct.  
:15:17 22 Q. But your testimony both at your deposition and at the  
:15:22 23 arbitration, to the best of your recollection, was all  
:15:26 24 accurate?  
:15:26 25 A. Yes.

Rohr - cross

:15:27 1 Q. Are you represented today by anyone?

:15:29 2 A. No.

:15:30 3 Q. In preparing for yesterday and today's testimony, did  
:15:34 4 you meet with Dr. Scott and Scuderi's attorneys?

:15:38 5 A. No. I did have dinner the night before with Mr.

:15:44 6 Buchdahl. And he basically was telling me when to show up

:15:48 7 and how this would differ in the rules of how the Court

:15:51 8 would be managed. But we didn't discuss the case in any

:15:54 9 detail or any of the facts of the case at all.

:15:56 10 Q. Did you have any phone discussions at all?

:15:58 11 A. No.

:15:59 12 Q. Did you, yourself, read through anything before your  
:16:01 13 testimony?

:16:02 14 A. The only thing I read through is I just looked at the  
:16:06 15 patents again.

:16:09 16 MR. COTTRELL: One minute, Your Honor.

:16:11 17 THE COURT: Sure.

:16:12 18 (Pause.)

:16:16 19 MR. COTTRELL: Thank you, Your Honor. Thank  
:16:18 20 you, Doctor. That's all I have.

:16:19 21 THE COURT: Redirect, counsel.

:16:23 22 MR. BUCHDAHL: Yes, Your Honor.

:16:25 23 THE COURT: Okay.

:16:26 24 REDIRECT EXAMINATION

:16:27 25 BY MR. BUCHDAHL:

Rohr - redirect

:16:39 1 Q. Dr. Rohr, first in response to that last line of  
:16:43 2 questions, just to be clear, I didn't prepare you for what  
:16:46 3 my questions to you at this proceeding would be, did I?

:16:50 4 A. Not at all. You made it very clear you wouldn't  
:16:52 5 discuss any elements of the case.

:16:53 6 Q. Let's go back over some of the things that counsel for  
:17:01 7 Zimmer questioned you about yesterday and today. If you  
:17:04 8 have still before you Plaintiffs' Exhibit 14 and 24, the  
:17:07 9 medical literature referring to the mobile-bearing and  
:17:12 10 fixed-bearing flex products?

:17:15 11 A. Yes.

:17:15 12 Q. If we could put up on the screen just by way of  
:17:19 13 example Plaintiffs' Exhibit 14, Page 2?

:17:22 14 If we could blow up the names listed on the  
:17:29 15 upper left-hand corner.

:17:30 16 Now, counsel for Zimmer pointed out yesterday  
:17:39 17 that your name wasn't listed here. Correct?

:17:42 18 A. That's correct.

:17:43 19 Q. And he also pointed out that not all of the named  
:17:46 20 inventors on the patent, the '729 patent, were listed in  
:17:52 21 this literature. Correct?

:17:52 22 A. Correct.

:17:53 23 Q. But isn't it the case that every inventor who is not  
:17:56 24 listed here was a Zimmer employee?

:17:59 25 A. I am sorry. What was the question?

Rohr - redirect

:18:01 1 Q. Those inventors who are not listed here all worked for  
:18:05 2 Zimmer. Correct?

:18:06 3 A. That's correct.

:18:06 4 Q. So this simply listed those people outside of Zimmer  
:18:10 5 who helped develop --

:18:12 6 THE COURT: Don't lead your witness, counsel.

:18:14 7 BY MR. BUCHDAHL:

:18:17 8 Q. Can we look for a moment at Defendants' Exhibit 106,  
:18:21 9 which is the declaration for patent application.

:18:31 10 A. Yes.

:18:31 11 Q. You were asked by counsel for Zimmer to sign this  
:18:35 12 document. Correct?

:18:36 13 A. That's correct.

:18:36 14 Q. And can we blow up for a moment the paragraph on the  
:18:42 15 second page of this exhibit that begins, "I believe," it's  
:18:50 16 the third paragraph. "I believe I am the original..."

:19:00 17 If you look at that paragraph, Dr. Rohr, you can  
:19:02 18 look at the rest of the paragraphs in this declaration, do  
:19:07 19 you recall anything about this document that asked you to  
:19:10 20 declare that this was a full list of all the inventors  
:19:13 21 involved?

:19:33 22 A. I don't see anything that indicates that that includes  
:19:36 23 all of the inventors.

:19:37 24 Q. And while you found it curious that Dr. Scott wasn't  
:19:41 25 mentioned here, you left it up to the attorneys to decide

Rohr - redirect

:19:47 1 who should be mentioned?

:19:48 2 A. Yes.

:19:48 3 Q. And those were Zimmer attorneys. Right?

:19:51 4 A. That's correct.

:19:51 5 Q. Now, yesterday, counsel asked your opinion of Audrey  
:19:55 6 Beckman. Do you recall that?

:19:57 7 A. Yes, I do.

:19:58 8 Q. Did Ms. Beckman accompany you during all of your  
:20:03 9 discussions with the surgeons at ISK about the flex issues  
:20:06 10 that we have been talking about?

:20:07 11 A. No.

:20:08 12 Q. Why not?

:20:10 13 A. Well, there were numerous times where, for instance,  
:20:16 14 we had -- well, a good example was one of the times like,  
:20:21 15 for instance, when John was particularly perturbed about the  
:20:24 16 problems we had with the PS-2 and whether it was still going  
:20:28 17 to be put on the market. Those were very challenging  
:20:33 18 discussions, to which Audrey Beckman had no reason to be  
:20:37 19 there, at her level and her involvement and what she did in  
:20:40 20 the company.

:20:41 21 There were also times when very clearly, by John  
:20:47 22 Insall and Norm Scott and I working together as physicians,  
:20:51 23 we could hammer out clinical issues which she had no  
:20:54 24 knowledge or basis to understand.

:20:55 25 So there were times we would have sessions that

Rohr - redirect

1 might start out with one reason to do so, where we were  
2 going to discuss issues with what was wrong with the PS and  
3 how we were going to look into trying to change the design.  
4 And at the same time then we could just as easily launch  
5 into very frequently how we were going to change the Legacy  
6 and discussions about flex and other areas.

7 There were times when I went to, for instance,  
8 we went to Europe to do some original prototype testing of  
9 the mobile-bearing knee. And Audrey didn't go with us.  
10 That was primarily John Insall, myself, and some European  
11 surgeons working in an operating room, et cetera. So there  
12 were many times Audrey wasn't with me for very good reasons.

13 Q. And there were specifically times that you met with  
14 Dr. Scott and had discussions about the flex implant where  
15 Ms. Beckman wasn't present. Correct?

16 A. That's correct.

17 Q. And did you also work with Dr. Scuderi at times when  
18 Ms. Beckman was not present?

19 A. Yes.

20 Q. Let's look for a moment at Exhibit 79 that you were  
21 just asked about this morning, if we could put that up on  
22 the screen?

23 In the first sentence here, you referred to a  
24 very extensive discussion between myself and Dr. Insall  
25 concerning his ideas for the next version of a new Zimmer



Rohr - redirect

:22:29 1 knee system. And you talk about the mobile-bearing knee  
:22:32 2 system. Did you mean to exclude Dr. Scott from this  
:22:38 3 description of these discussions?

:22:40 4 A. No.

:22:40 5 Q. And to what extent did Dr. Scott participate in these  
:22:44 6 discussions?

:22:47 7 A. Here today, I can't tell you whether he was at the  
:22:49 8 meeting with John and I when we discussed this. Again, part  
:22:57 9 of the way the system works is, certainly, John was the  
:23:01 10 senior member. And at this point it was just to get  
:23:05 11 established some background for the patent people to be  
:23:08 12 aware that we were having discussions about an entirely new  
:23:12 13 knee system. And that is all this was meant to document, is  
:23:17 14 that there were certain features when we started to have  
:23:19 15 this discussion. And this is the type of thing patent  
:23:23 16 lawyers asked us as company lawyers to do, at least document  
:23:26 17 when we started these discussions, and then they would give  
:23:29 18 further instructions of what kind of things should be done,  
:23:31 19 and they would start to make inquiries of what were the  
:23:34 20 various features and what might be novel about it.

:23:37 21 This was a typical thing we were asked to do.  
:23:39 22 Since this got to be a very detailed discussion about an  
:23:42 23 entirely new implant and there was no engineers to document  
:23:44 24 all the little details they usually keep track of, this is  
:23:48 25 the kind of thing I was asked to do by Paul Schoenle, the

Rohr - redirect

:23:52 1 lead pertinent person in the patent department, and that's  
:23:54 2 what this represents.

:23:55 3 Q. And as those discussions continued, with regard to the  
:24:00 4 '729 patent, was Dr. Scott involved?

:24:03 5 A. Yes.

:24:03 6 Q. Did you also have meetings with Dr. Scuderi present?

:24:09 7 A. Yes.

:24:09 8 Q. Let's look for a moment at the sketch that was put up  
:24:16 9 on the screen for a while yesterday. It's marked as  
:24:19 10 Defendants' Exhibit 110. I believe you were asked when you  
:24:24 11 first saw this sketch, Dr. Rohr. Could you remind us of  
:24:30 12 when you first recall seeing this document?

:24:35 13 A. Again, I can't tell you exactly when I first saw it.  
:24:40 14 When I was shown this, I think, during the deposition, I  
:24:43 15 remembered having seen it before. But I obviously don't  
:24:46 16 remember when.

:24:46 17 Q. Now, do you recall yesterday counsel for Zimmer asked  
:24:49 18 you if you had discussed this with Dr. Scott and you asked  
:24:52 19 if counsel meant discussed the sketch or discussed the  
:24:55 20 concept shown in the sketch? And counsel said, the sketch  
:24:58 21 itself. Do you recall that exchange?

:24:59 22 A. Yes, I do.

:25:00 23 Q. Well, now, let me ask you a question that Zimmer's  
:25:03 24 counsel didn't ask. Did you discuss the concept shown in  
:25:07 25 the sketch with Dr. Scott?

Rohr - redirect

:25:08 1 A. Yes.

:25:08 2 Q. And the concept being the thickening of the condyles.

:25:12 3 Correct?

:25:13 4 A. Yes. Again, I am sorry, but it's a technical issue.

:25:18 5 The issue of trying to create higher flexion by deepening

:25:22 6 this posterior recess, which one manifestation of which is

:25:27 7 potentially actually thickening of that condyle.

:25:30 8 Q. So we have the time frame right, these discussions

:25:33 9 first occurred while you were working with the ISK surgeons

:25:36 10 in developing a Legacy. Correct?

:25:38 11 A. It may have even been before the actual Legacy.

:25:41 12 Q. So no later than 1995, certainly?

:25:44 13 A. That's correct.

:25:44 14 Q. Now, counsel raised the issue of cam-and-spine

:25:52 15 interaction in this full flexion knee. Did you discuss that

:25:55 16 concept with Dr. Scott?

:25:57 17 A. Yes.

:25:58 18 Q. What do you recall discussing with him?

:26:02 19 A. Norm Scott had presented many times, when we were

:26:05 20 young physicians and occasionally we were asked to appear on

:26:09 21 opposite sides of an issue, of whether we should be cruciate

:26:16 22 retaining surgeons or cruciate sparing, cruciate retaining

:26:22 23 versus sacrifice, in PS design. Even though I used both

:26:25 24 designs, we used to debate it. And one of the things I used

:26:27 25 to use in the debate, one of the problems with the posterior

Rohr - redirect

1 stabilizer was this ability for them to jump, where they  
2 would dislocate. And Norm would even give me a case  
3 sometimes when it was a stump the other guy business that  
4 goes on in those meetings and show me one that was being  
5 dislocated.

6 It was an issue that I know he was very  
7 sensitive to. I believe he has written articles on it or  
8 discussed it.

9 So I talked to both Norm, particularly, and also  
10 John, but particularly Norm, about why was this happening  
11 and how much of a problem was it, because it really wasn't  
12 public knowledge as to how frequent it was actually  
13 occurring. And Norm, I knew, was the best source in  
14 understanding to what degree that was occurring.

15 Q. Let me ask you one more question about these sketches.

16 We looked at the sketch from Dr. Insall. You  
17 said that you prepared a very similar sketch, maybe around  
18 the same time, maybe somewhat earlier. Correct?

19 A. Yes.

20 Q. Now, you are not aware of any of the six Zimmer  
21 engineers who are named as inventors helping you with that  
22 sketch. Correct?

23 THE COURT: Counsel, I will ask again. I am  
24 going to direct this comment to all lawyers. He is your  
25 witness. Don't lead him. Even though it is not drawing

Rohr - redirect

:27:43 1 objections, I find it objectionable.

:27:45 2 MR. BUCHDAHL: I apologize.

:27:46 3 BY MR. BUCHDAHL:

:27:48 4 Q. Did any one of the named inventors help you with the  
:27:52 5 sketch that you prepared?

:27:53 6 A. No.

:27:53 7 Q. Are you aware of any of the named inventors helping  
:27:59 8 Dr. Insall with the sketch that he prepared?

:28:02 9 A. No.

:28:02 10 Q. Let's turn now, if we can put it up on the screen, to  
:28:10 11 the '729 patent. You referred today to what you described  
:28:19 12 as the nuts and bolts of this patent. I want to look at the  
:28:23 13 language of Claim 1 for a moment, which is the very last  
:28:28 14 page of this exhibit.

:28:29 15 If we could highlight the following words.

:28:36 16 There is a reference in Claim 1 to a superior condyle  
:28:41 17 extending superiorly from the distal condyle to form a  
:28:45 18 superior articular surface.

:28:48 19 Then a little further down, it says, the  
:28:53 20 superior condyles extend the articular surface back to  
:28:58 21 accommodate flexion of at least 160 degrees, kind of  
:29:03 22 skipping over some of the words, but that last section.

:29:05 23 Dr. Rohr, is this part of what you were talking  
:29:12 24 about when you refer to the nuts and bolts of this patent?

:29:15 25 A. Yes. Again, it's the -- when I use the term nuts and

Rohr - redirect

1 bolts, I am talking about -- just as I understand why this  
2 is supposedly the independent claim, it's the primary claim,  
3 is that this ability to change the shape and particularly  
4 the thickness and deepen that recess is what makes the whole  
5 device unique and what could dramatically the performance of  
6 the kinematics of this component.

7 Everything after that is just features and how  
8 you actually accomplish it in metal and those others are  
9 just kind of variations of a theme. This is the heart, what  
10 I call the nuts and bolts, in engineering terms, that's what  
11 we speak of, of what makes this that unique concept.

12 Q. Did Dr. Scott contribute to these nuts and bolts of  
13 this '729 patent?

14 A. Yes.

15 Q. How did he do so?

16 A. Early in this discussion, when this became a reality  
17 of trying to create an implant to do this for Asia, John  
18 Insall, Norm Scott and I spent hours in John Insall's office  
19 around the table he had in his office hammering out both --  
20 as I mentioned once before, John Insall really had a great  
21 intuitive sense about implants. But sometimes when I tried  
22 to convey to him the engineering concept, in other words,  
23 this issue of whether you extended the radius back versus  
24 shorten the box, for some reason I couldn't get that across  
25 to John.

Rohr - redirect

:30:52 1 And I remember Norm getting deeply involved in  
:30:55 2 the middle of that discussion, because it was germane to how  
:30:58 3 we would do the clinical work and the radiographic work to  
:31:03 4 determine what was the correct answer.

:31:04 5 We didn't know whether the correct answer was  
:31:06 6 one or the other or a combination thereof.

:31:09 7 So very early, before any of the other engineers  
:31:13 8 really got involved, we were trying to hammer out this  
:31:16 9 concept of, this difference, which may to laypeople seems  
:31:21 10 subtle, but to clinicians it is deeply different. For an  
:31:25 11 engineers it is critical, because it determines aspects of  
:31:29 12 strength and how you design the molds, et cetera.

:31:32 13 So there are things you can do and can't do in  
:31:35 14 metal, so it's very important to get this concept down, and  
:31:39 15 which was the right concept.

:31:40 16 I have stated before that even this patent  
:31:43 17 doesn't pull in all of what I was trying to say. To this  
:31:47 18 day, a lot of people still don't get it.

:31:50 19 Q. Did Dr. Scott get it?

:31:52 20 A. Yes.

:31:53 21 Q. Did Dr. Scott contribute to this concept at the end of  
:32:04 22 the claim of achieving at least 160 degrees of flexion?

:32:07 23 MR. COTTRELL: Your Honor, I have been patient.  
:32:08 24 I think this is getting a little beyond the scope of cross.  
:32:11 25 I didn't go through each element of Claim 1.

Rohr - redirect

:32:15 1 THE COURT: I think you are right.

:32:18 2 MR. COTTRELL: It is also eliciting some

:32:20 3 hearsay. Dr. Scott is going to be here.

:32:22 4 MR. BUCHDAHL: Your Honor, a couple of things.

:32:23 5 First of all, there was a suggestion on cross yesterday that

:32:26 6 this patent in sum an substance was simply thickening the

:32:28 7 condyles. And the suggestion was made during cross that

:32:31 8 this entire invention was accomplished through this sketch.

:32:34 9 And I think it's permissible to go through the patent and

:32:38 10 show that these claims call out a lot more than just

:32:41 11 thickening the condyles, so we have a full sense of what

:32:44 12 this patent is about.

:32:45 13 We also had questions this morning which I am

:32:48 14 about to get to about the cam and spine which are mentioned

:32:51 15 in Claims 4 and 6. And I want to ask the witness in

:32:54 16 response to the questions on cross about those claims.

:32:56 17 THE COURT: Does the fact-finder need to have

:32:58 18 the information you just suggest was sort of glossed over to

:33:02 19 understand what the contribution of the plaintiffs was to

:33:06 20 the effort?

:33:07 21 MR. BUCHDAHL: Yes, Your Honor.

:33:08 22 THE COURT: What is your view?

:33:09 23 MR. COTTRELL: Your Honor, my view is, it's

:33:11 24 still, I believe, beyond the scope of cross. Dr. Scott will

:33:16 25 be live. And also we have two experts in this case.



Rohr - redirect

:33:18 1 THE COURT: I am going to sustain the objection.

:33:20 2 MR. BUCHDAHL: Your Honor --

:33:21 3 THE COURT: I will sustain the objection,

:33:22 4 counsel. Move on.

:33:23 5 MR. BUCHDAHL: May I show the witness two other

:33:26 6 parts of the patent itself?

:33:27 7 THE COURT: Yes. Let's see what you have to ask

:33:29 8 him.

:33:30 9 BY MR. BUCHDAHL:

:33:31 10 Q. Would you look at Claim 4 for a moment.

:33:33 11 MR. COTTRELL: Your Honor --

:33:35 12 THE COURT: Counsel, you are going to have Dr.

:33:37 13 Scott. And you are going two experts.

:33:40 14 MR. BUCHDAHL: Right. If I may, Your Honor --

:33:43 15 THE COURT: Is Dr. Scott going to talk about his

:33:46 16 contribution?

:33:46 17 MR. BUCHDAHL: Yes. And --

:33:48 18 THE COURT: Counsel.

:33:48 19 Has Dr. Rohr not, in his best effort, attempted

:33:52 20 to describe to all of us what Dr. Scott's contribution was

:33:55 21 to the patent? And furthermore -- this is a compound

:33:59 22 question -- did you not have an opportunity on direct

:34:02 23 initially to go into this level of detail with the doctor?

:34:05 24 MR. BUCHDAHL: I did have that opportunity.

:34:07 25 THE COURT: Sustained.

Rohr - redirect

:34:15 1 MR. BUCHDAHL: If I can have one minute, Your  
:34:17 2 Honor.

:34:17 3 THE COURT: Yes.

:34:18 4 (Pause.)

:34:35 5 BY MR. BUCHDAHL:

:34:35 6 Q. Dr. Rohr, just one more question. Recognizing, as you  
:34:38 7 said, that you are not a patent attorney, based on your  
:34:42 8 firsthand observations of Dr. Scott's contributions to  
:34:45 9 what's claimed in the '729 patent, would you have included  
:34:49 10 him as an inventor on that patent?

:34:51 11 MR. COTTRELL: Your Honor --

:34:52 12 THE COURT: I will let him answer that.

:34:55 13 MR. COTTRELL: Thank you.

:34:57 14 THE WITNESS: Yes.

:34:57 15 MR. BUCHDAHL: Nothing further.

:34:58 16 THE COURT: Doctor, thank you. Have a safe  
:35:01 17 trip.

:35:01 18 THE WITNESS: Thank you very much.

19 (Witness excused.)

:35:13 20 THE COURT: Counsel, your next witness.

:35:14 21 MR. FRIEDMAN: Good morning, Your Honor.

:35:17 22 THE COURT: Good morning.

:35:18 23 MR. FRIEDMAN: Our next witness is Dr. Scuderi.

:35:21 24 Would you distribute the books, please, Mr.

:35:28 25 Grodin.

Scuderi - direct

:35:28 1 ... GILES R. SCUDERI, having been duly sworn as  
:35:47 2 a witness, was examined and testified as follows ...

:35:51 3 THE COURT: Good morning.

:35:53 4 THE WITNESS: Good morning.

:36:17 5 THE COURT: Counsel, you may proceed.

:36:19 6 DIRECT EXAMINATION

:36:20 7 BY MR. FRIEDMAN:

:36:21 8 Q. Could you please state your name for the record?

:36:23 9 A. Sure. Giles R. Scuderi.

:36:25 10 Q. Dr. Scuderi, what is your current occupation?

:36:28 11 A. I am an orthopedic surgeon.

:36:30 12 Q. As an orthopedic surgeon, is there any area that you  
:36:34 13 specialize in?

:36:36 14 A. I specialize in surgery of the knee.

:36:38 15 Q. And do you have any involvement in the development of  
:36:43 16 artificial knee implants?

:36:45 17 A. Yes, I do.

:36:46 18 Q. How long have you been a knee specialist?

:36:51 19 A. For almost 20 years.

:36:54 20 Q. What is your current position?

:36:59 21 A. Orthopedic surgeon at Lenox Hill Hospital and Franklin  
:37:04 22 General Hospital in New York.

:37:04 23 Q. What do you specialize in at Lenox Hill and Franklin?

:37:09 24 A. Orthopedic surgery.

:37:10 25 Q. And does this include reconstructive knee surgery?

Scuderi - direct

:37:15 1 A. Yes, it does.

:37:16 2 Q. Do you hold any professorships?

:37:18 3 A. I do. I am an assistant clinical professor in  
:37:22 4 orthopedics at Albert Einstein College of Medicine.

:37:25 5 Q. Let's briefly discuss ISK, the Insall Scott Kelly  
:37:31 6 Institute. What is the Insall Scott Kelly Institute?

:37:34 7 A. The Insall Scott Kelly Institute is an orthopedic  
:37:37 8 practice in New York. It comprises several orthopedic  
:37:42 9 surgeons. We have a clinical practice, fellowship, and a  
:37:46 10 research component.

:37:46 11 Q. Is there an area of concentration for ISK?

:37:52 12 A. If we can consider all the group, we do have various  
:37:55 13 specialties. But the primary focus is certainly the knee.

:37:58 14 Q. And what is your position with ISK?

:38:04 15 A. I am one of the directors of the institute.

:38:05 16 Q. Where did you go to college and what degree did you  
:38:09 17 receive?

:38:10 18 A. Went to St. John's University in New York, received a  
:38:14 19 Bachelor of Science degree in biology.

:38:17 20 Q. I presume you received a medical degree. So tell us,  
:38:21 21 if you would, where you received it from and when?

:38:23 22 A. I graduated from the State University of New York  
:38:26 23 Downstate Medical Center in Brooklyn. I graduated in 1982.

:38:33 24 Q. Following medical school, you did an internship?

:38:37 25 A. Yes, I did.

Scuderi - direct

:38:38 1 Q. And you did a residency?

:38:40 2 A. Yes.

:38:41 3 Q. Where was your residency?

:38:44 4 A. So I did my internship at the State University of New

:38:48 5 York Downstate Medical Center, and my residency program was

:38:51 6 at Lenox Hill Hospital in New York.

:38:53 7 Q. What area was the residency in?

:38:56 8 A. Orthopedic surgery.

:38:58 9 Q. After your residency, did you do a fellowship?

:39:00 10 A. Yes, I did.

:39:01 11 Q. Where did you do the fellowship?

:39:04 12 A. At the Hospital for Special Surgery on the Knee

:39:08 13 Service with Dr. Insall.

:39:09 14 Q. What period of time was your fellowship?

:39:12 15 A. 1987 to 1988.

:39:14 16 Q. And is that where you met Dr. Insall?

:39:17 17 A. I had met Dr. Insall about a year prior during the

:39:22 18 interview process, and during that year spent the whole time

:39:26 19 with him.

:39:26 20 Q. During the year of your fellowship?

:39:28 21 A. That's correct.

:39:28 22 Q. When did you meet Dr. Scott?

:39:31 23 A. I met Dr. Scott for the first time during my interview

:39:35 24 for the orthopedic training program at Lenox Hill Hospital.

:39:39 25 He was the residency director. So I spent the four years

Scuderi - direct

:39:42 1 with him there at Lenox Hill.

:39:44 2 Q. How long was the fellowship at the Hospital for

:39:49 3 Special Surgery?

:39:49 4 A. It was one year, 1987 to 1988.

:39:52 5 Q. What did you do following the fellowship?

:39:56 6 A. Following the fellowship, I went into private practice  
:39:59 7 on Long Island for a few years. And I was also an attending  
:40:04 8 in the Orthopedic Knee Clinic for Special Surgery with Dr.  
:40:10 9 Insall.

:40:10 10 Q. When did you join ISK?

:40:14 11 A. I joined the ISK group in 1992.

:40:18 12 Q. How is it you came to join ISK in 1992?

:40:22 13 A. I was invited by Dr. Scott and Dr. Insall to join the  
:40:26 14 group.

:40:26 15 Q. And why did you join?

:40:28 16 A. I was excited. I mean, it was a great opportunity to  
:40:32 17 work with Dr. Insall and Dr. Scott. They were world  
:40:36 18 renowned surgeons. I could focus my practice almost  
:40:40 19 entirely on the knee.

:40:45 20 Q. Have you been associated with ISK since 1992?

:40:50 21 A. Yes.

:40:50 22 Q. Now, let's discuss generally your period of work at  
:40:59 23 ISK. Did you work closely with Dr. Insall while you were  
:41:03 24 both at ISK?

:41:05 25 A. Yes.

Scuderi - direct

:41:06 1 Q. Would you describe to the Court how you worked closely  
:41:11 2 with Dr. Insall and what capacities or connections during  
:41:15 3 that period prior to his death?

:41:16 4 A. So when I was invited to join the ISK group, John  
:41:23 5 wanted a super fellow, he wanted me to be. He wanted a  
:41:27 6 junior associate to spend all the time with him, to see  
:41:29 7 patients with him, operate with him on a regular and daily  
:41:33 8 basis. We did clinical research together. We did  
:41:35 9 development work together. I was with him every day, almost  
:41:37 10 every hour of the day.

:41:38 11 Q. Let me ask you this question: Would you consider  
:41:47 12 yourself to have been his surgical partner?

:41:49 13 A. Yes, absolutely. Almost every case that John did I  
:41:52 14 operated with him.

:41:53 15 Q. And have you worked closely with Dr. Scott?

:41:57 16 A. Yes.

:41:59 17 Q. And describe to the Court how you have worked closely  
:42:03 18 with Dr. Scott while at ISK, particularly with reference to  
:42:07 19 the 1990s?

:42:08 20 A. Sure. At that time, again, we were very close. We  
:42:11 21 saw patients together. We operated together. We did  
:42:15 22 research projects together. It was very much a very  
:42:18 23 close-knit group in which we spent almost -- we spent every  
:42:23 24 day together. We were involved in conference, the  
:42:28 25 fellowship training program, a great deal of activities.

Scuderi - direct

:42:31 1 Q. How would you regard Dr. Insall's character?

:42:36 2 A. John was a great man. He was almost like another

:42:39 3 father to me. He was a very ethical, honest person.

:42:42 4 Q. Have you published any articles?

:42:47 5 A. Yes, I have.

:42:48 6 Q. And how many articles have you published?

:42:54 7 A. I have published 75 to 100 articles in various  
:42:58 8 orthopedic journals, peer-reviewed journals, the Journal of  
:43:02 9 Bone and Joint Surgery, Clinical Orthopedics Research,  
:43:04 10 Journal of Arthroplasty. Just to name a few.

:43:07 11 Q. Do you give any lectures on knee replacements, either  
:43:13 12 total or revision?

:43:16 13 A. Yes, I do.

:43:17 14 Q. And how many such lectures do you give a year?

:43:22 15 A. I may give about 30 or 40 lectures a year. I travel  
:43:26 16 nationally and internationally to lecture on surgery of the  
:43:30 17 knee, especially total knee arthroplasty as well as revision  
:43:33 18 arthroplasty.

:43:34 19 Q. Are you on the editorial board of any publications?

:43:37 20 A. Yes, I am.

:43:37 21 Q. What is that?

:43:39 22 A. Journal of Knee Surgery and Techniques in Knee  
:43:43 23 Surgery.

:43:43 24 Q. Now, Dr. Rohr testified concerning an organization  
:43:48 25 called the Knee Society. I will just ask you simply, are



Scuderi - direct

:43:52 1 you a member of the Knee Society?

:43:54 2 A. Yes, I am.

:43:55 3 Q. How long have you been a member of the Knee Society?

:43:58 4 A. I believe since about 1995.

:44:00 5 Q. And have you held any leadership positions in the Knee

:44:04 6 Society?

:44:04 7 A. Yes. I am currently the president of the Knee

:44:06 8 Society.

:44:06 9 Q. And is the Knee Society conducting any study that you

:44:14 10 are involved in?

:44:16 11 A. I am actually the chairman of the new knee scoring

:44:21 12 system. Over the last four years we have had a committee

:44:24 13 which I chair looking at outcomes of total knee replacement

:44:27 14 and we have developed a knee score. It's been validated and

:44:32 15 recently published in Clinical Orthopedics just this year.

:44:34 16 Q. How many total knee replacements do you perform a

:44:38 17 year?

:44:40 18 A. Between primary and revision arthroplasty, about three

:44:43 19 to three-fifty.

:44:44 20 Q. And are you a consultant to Zimmer now?

:44:47 21 A. Yes, I am.

:44:49 22 Q. Without disclosing any of confidential information,

:44:54 23 what types of things are you doing for Zimmer?

:44:58 24 A. I am currently a design and development surgeon for

:45:00 25 Zimmer as well as a consultant on total knee products.

Scuderi - direct

:45:04 1 Q. All right. Let's discuss the knee. We will do some  
:45:13 2 anatomy 101, which I think will be helpful.

:45:18 3 Can we have a picture of the knee joint up here?

:45:23 4 Would you just explain -- do you have a laser  
:45:25 5 pointer? I think this will be helpful as we go through the  
:45:35 6 next section.

:45:37 7 MR. FRIEDMAN: May I approach?

:45:38 8 THE COURT: You may approach.

:45:40 9 MR. FRIEDMAN: Thank you, Your Honor.

:45:42 10 BY MR. FRIEDMAN:

:45:43 11 Q. Do you know how to use it?

:45:46 12 A. I think so.

:45:49 13 Q. Could you explain to the Court what the knee joint  
:45:57 14 consists of?

:46:00 15 A. So as you see here, this is a front view of a normal  
:46:04 16 knee. Once you go underneath the skin and the soft tissue,  
:46:10 17 underneath the muscles and tendons, there are three major  
:46:13 18 bones that comprise the knee joint: the femur, which is the  
:46:16 19 thigh bone, the tibia -- the shin bone -- and the kneecap.  
:46:19 20 This is covered by articular cartilage that is the  
:46:21 21 smooth-like shiny cartilage at the ends. This forms the  
:46:24 22 articular surface. It's supported by a number of ligaments.

:46:31 23 And the knee has complex motion. It flexes, it  
:46:35 24 rolls back, and it rotates.

:46:37 25 Q. Could you explain the differences among lateral,

Scuderi - direct

:46:49 1 medial, anterior and posterior?

:46:52 2 A. As a matter of direction, the lateral side is the  
:46:55 3 outer side of the joint. The medial is the inner side of  
:46:59 4 the joint. And when we describe anterior and posterior, if  
:47:03 5 we look at a side-view of the body, anterior obviously is  
:47:06 6 the front, and posterior is the back.

:47:10 7 Q. Now, what is the characteristic or what are the  
:47:13 8 characteristics of a healthy knee? When we look at a  
:47:19 9 healthy knee, what do we see?

:47:24 10 A. A healthy knee has normal straight alignment. It's  
:47:28 11 stable, has a good deal of motion to it. On average,  
:47:35 12 straight zero normal motion is about an average of 135  
:47:39 13 degrees of flexion. You see here again, supporting by the  
:47:42 14 ligaments, and the major ligaments is the lateral  
:47:46 15 collateral, it is the lateral side, the medial collateral,  
:47:49 16 MCL. The ACL is the anterior cruciate ligament. It is torn  
:47:53 17 by many athletes in sporting activities.

:47:55 18 The PCL, again, and the fourth litigation that  
:47:59 19 provides stability to the knee.

:48:00 20 Q. While we have this up on the board, and since there is  
:48:05 21 going to be a good deal of testimony about it, what is the  
:48:09 22 PCL and what function does it serve?

:48:13 23 A. The role of the PCL is to provide stability to the  
:48:16 24 knee to posterior translation or posterior movement of the  
:48:20 25 tibia on the femur as the knee is flexed. Again, in

Scuderi - direct

:48:25 1 layman's terms, I tell my patients, it is a check rein. It  
:48:29 2 again provides one direction of stability.

:48:31 3 Q. Again, although it is not indicated here, what is this  
:48:38 4 area in here?

:48:41 5 A. So in this area here, these are the menisci, actually,  
:48:44 6 in this drawing, that is the lateral meniscus and the medial  
:48:50 7 meniscus, and that is the articular tibial articulation.

:48:52 8 Q. And you have told us about the characteristics of a  
:48:57 9 healthy knee. What are the characteristics of an unhealthy  
:49:02 10 knee?

:49:02 11 A. Well, there is many reasons why a knee could be  
:49:05 12 unhealthy. There could be a traumatic injury a ligament,  
:49:08 13 just as I mentioned, the ACL being the common injury or a  
:49:12 14 torn meniscus. We hear commonly of the torn cartilage.  
:49:16 15 Then there is damage to the articular surface.

:49:18 16 There may be a fracture, there may be  
:49:21 17 post-traumatic arthritis, degenerative arthritis, which is a  
:49:23 18 very common condition, involving a great many patients in  
:49:27 19 our practice. As well as inflammatory conditions, such as  
:49:29 20 rheumatoid arthritis, gout. These create damage to the  
:49:32 21 articular surface, requiring treatment.

:49:35 22 Q. And the articular surface is the surface that is shown  
:49:40 23 here that interfaces with the tibia, the top of the tibia?  
:49:48 24 That's an articular surface?

:49:50 25 A. Yes. Where you see on this diagram it says articulate

Scuderi - direct

:49:53 1 cartilage. Again, that's the smooth white shiny end of the  
:49:56 2 bone. The femur articulates with the tibia, and you also  
:49:59 3 have articulate cartilage on the back of the kneecap, and  
:50:02 4 you can see here where it's pointing to articulate  
:50:04 5 cartilage. This is the trochia or the groove. This is  
:50:08 6 where your kneecap sits as the knee flexes and extends.  
:50:12 7 Q. I think you had indicated -- let's talk about an  
:50:17 8 arthritic knee. An arthritic knee is caused by what?  
:50:22 9 A. In general, most of arthritis is osteoarthritis, that  
:50:26 10 is degenerative arthritis of the knee joints, wear and tear.  
:50:29 11 There are other conditions, such as inflammatory arthritis.  
:50:33 12 As I mentioned earlier, you know, rheumatoid arthritis,  
:50:37 13 gout, and then obviously post-traumatic, somebody may have  
:50:40 14 had an injury or fracture with damage to the articulate  
:50:43 15 cartilage. It never heels back smooth. And this may lead  
:50:46 16 to an arthritic joint.  
:50:47 17 Q. By the way, what is the effect on the patient when  
:50:49 18 this happens? What are the symptoms?  
:50:52 19 A. The symptoms of arthritis are one of pain and  
:50:54 20 disability. They have limited range of motion, a crooked  
:50:57 21 knee, and they want something done because they are not  
:51:00 22 enjoying life.  
:51:01 23 Q. Now, I would like to move to another subject, which  
:51:07 24 follows logically from this, that is the total knee  
:51:11 25 replacement, which is sometimes referred to as TKR?

Scuderi - direct

:51:15 1 A. Yes.

:51:15 2 Q. Would you explain to the Court what a total knee  
:51:19 3 replacement is?

:51:22 4 A. A total knee replacement is just really what the term  
:51:26 5 says, it's a replacement of the joint. We actually  
:51:28 6 resurface the end of the arthritic knee. We put a cap on  
:51:32 7 the femur, a cap on the tibia, and many times a cap on the  
:51:35 8 kneecap. So we want to reestablish the smooth articulation,  
:51:38 9 so we can correct the deformity, realign the knee, give them  
:51:43 10 back their motion and relieve them of their pain and  
:51:46 11 discomfort that they are experiencing.

:51:47 12 It is that major surgical procedure.

:51:50 13 MR. FRIEDMAN: Your Honor, may I hand the  
:51:51 14 witness an exhibit?

:51:52 15 THE COURT: Sure.

:51:58 16 MR. FRIEDMAN: Let me indicate for the record  
:52:00 17 that this exhibit consists of three pieces, DTX-468,  
:52:07 18 DTX-469, and DTX-472.

:52:09 19 THE COURT: Would you let counsel examine it.

:52:13 20 MR. FRIEDMAN: They gave it to me.

:52:15 21 THE COURT: They gave it to you.

:52:16 22 MR. FRIEDMAN: Pardon me. They loaned it to me.

:52:19 23 BY MR. FRIEDMAN:

:52:20 24 Q. I think that the exhibit will help you explain to the  
:52:35 25 Court what a total knee replacement is. It's up on the

Scuderi - direct

1 board.

2 MR. FRIEDMAN: We also have a device if you want  
3 to examine it.

4 THE WITNESS: So the component parts that I have  
5 been handed are three parts, which are the major component  
6 parts of a knee replacement.

7 THE COURT: Does counsel need to move to be able  
8 to see?

9 MR. HALES: I am okay.

10 THE WITNESS: We have the FEMORAL component,  
11 which is identified on the illustration, it's a side view.  
12 This is this component part. This goes on the end of the  
13 thigh bone. We have the tibial base plate, which is marked  
14 as a tibial tray. That goes on the upper end of the tibia.

15 Then we have the bearing, which is a  
16 polyethylene insert. So this gets assembled and implanted  
17 in the patient.

18 In the surgical technique, many patients think  
19 we actually cut out your knee joint and put a prosthesis in.  
20 We actually don't do that. We have special surgical  
21 instruments that give us very precise cuts. And I usually  
22 describe it as a sculpturing of the end of the bone, because  
23 I need to restore the alignment, looking at it straight, as  
24 well as, if you think of somebody that is bow-legged or  
25 knocked-kneed, you want to correct that alignment, you want

Scuderi - direct

:53:52 1 it straight in the front, straight in the sagittal view,  
:53:56 2 straight in the frontal view. So I want to straighten out  
:53:59 3 the mechanical alignment of the knee joint. You sculpture  
:54:02 4 the end of the bone and the kneecap. I put the cap on the  
:54:05 5 end of the bone and in the proper alignment, rotation and  
:54:09 6 position, restoring the anatomy.

:54:11 7 I want to also then put that new cap on the  
:54:13 8 tibia because I need to make the parts together again with  
:54:16 9 precision instruments. I cut the upper surface of the  
:54:21 10 tibia, insert the tray. Then in balancing the knee joint,  
:54:23 11 because you want it stable too, we insert these plastic  
:54:27 12 bearings. And they come in various thicknesses. It is the  
:54:31 13 interaction, as we come together, this is what the patient  
:54:33 14 actually walks on -- I am I am trying to hold it together.  
:54:36 15 This is what the patient walks on. This is how the knee  
:54:39 16 bends. This is the type of flexion and motion that we try  
:54:42 17 to achieve in our patients.

:54:43 18 Q. Now, you are familiar with the term fixed implant and  
:54:50 19 mobile implant. Correct?

:54:52 20 A. Yes.

:54:52 21 Q. They are different. Correct?

:54:54 22 A. Yes.

:54:54 23 Q. I would like to give the witness DTX-476, DTX-477,  
:55:02 24 which again, Zimmer's counsel has been kind enough to loan  
:55:06 25 to us.



Scuderi - direct

:55:20 1 Now, the two different sets of devices that I  
:55:23 2 gave you, they are Zimmer products. Correct?

:55:25 3 A. Yes.

:55:25 4 Q. What products are they, can you identify them?

:55:28 5 A. Yes, I can.

:55:29 6 Q. What are they?

:55:30 7 A. This is the LPS High-Flex femoral component. This is  
:55:36 8 a High-Flex fixed-bearing component.

:55:40 9 THE COURT: Doctor, for the record, if you could  
:55:41 10 refer to the numbers.

:55:43 11 THE WITNESS: Sure. So the femoral component is  
:55:45 12 DTX-469, High-Flex femoral component. The fixed-bearing is  
:55:52 13 DTX-468. And the components that I was just handed are  
:56:00 14 DTX-477 and 476. That's the mobile-bearing prosthesis.

:56:05 15 BY MR. FRIEDMAN:

:56:06 16 Q. Would you explain to the Court how the mobile-bearing  
:56:09 17 prosthesis works and what the difference is between that and  
:56:13 18 the fixed-bearing?

:56:15 19 A. Let me go back to the original device.

:56:17 20 This original device is the fixed bearing  
:56:21 21 implant, this is actually the picture that you have up.

:56:25 22 This tray sits on the tibia, the polyethylene,  
:56:27 23 the insert, locks in place.

:56:29 24 Q. Is that tray referred to as the poly?

:56:32 25 A. The base plate?

Scuderi - direct

:56:34 1 Q. What's in your right hand?

:56:36 2 A. Is in my left hand. The poly is the bearing surface.

:56:39 3 This is the articular surface. That polyethylene locks into  
:56:42 4 the tray.

:56:45 5 There is no movement between the undersurface of  
:56:48 6 the polyethylene and the tray. It's locked in as one piece.

:56:52 7 So when the knee flexes and extends, any  
:56:55 8 rotational movement occurs on the articular surface. So  
:57:01 9 flexion, extension, and that is the rotation.

:57:03 10 In contrast, mobile-bearing, the tray, as you  
:57:07 11 see, looks similar, this is a key piece, no locking  
:57:12 12 mechanism on the upper surface. Here is the locking  
:57:15 13 mechanism. In this particular case, on the LPS Flex mobile,  
:57:19 14 we have a trunnion, this little projection on the top. The  
:57:23 15 polyethylene actually sits on the trunnion. There is a  
:57:26 16 little hole underneath. It pops in place. This one is just  
:57:29 17 a little snug.

:57:30 18 And you can see here that -- this one is not  
:57:32 19 moving well. Okay, there we go.

:57:34 20 You can see here, I can rotate the plastic on  
:57:38 21 the base plate. Again, the same femoral component, flexion  
:57:43 22 and extension occurs at the bearing space, it's called just  
:57:47 23 the articular surface. But any rotational movement occurs  
:57:51 24 on the base plate on the -- this one doesn't move well. It  
:57:55 25 is just a tight fit. The lubrication of the body fluids

Scuderi - direct

:57:58 1 helps it move a little better.

:58:01 2 So the difference again, locked in place, all  
:58:04 3 the motion occurring at the articular surface, flexion,  
:58:08 4 extension, as well as rotation. Mobile-bearing, flexion,  
:58:11 5 extension, and rotation occurring on the base plate.

:58:13 6 Q. Thank you. Just leave those up there. We will pick  
:58:17 7 them up at the break.

:58:18 8 Now, as I stated in my opening, this case  
:58:25 9 involves PS devices. Correct?

:58:29 10 A. Yes.

:58:29 11 Q. And could you explain the different between a PS  
:58:35 12 device and a cruciate retaining or CR device? Can we put  
:58:41 13 something back up which will display the posterior cruciate  
14 ligament?

:58:52 15 So the question is, if you could for the Court,  
:58:58 16 with reference to the picture, if you think it will be  
:59:01 17 helpful, explain the different between PS and CR implant  
:59:07 18 devices generally?

:59:08 19 A. Let me at least define a posterior cruciate ligament  
:59:13 20 preserving knee. Again, just go back to this ligament right  
:59:16 21 here, the PCL, you can see on the illustration, is again, as  
:59:21 22 I mentioned earlier, one of the major ligaments in the knee  
:59:23 23 joint. It prevents the tibia from sloping back. There is a  
:59:27 24 school and a philosophy that that ligament should be  
:59:29 25 preserved. You will hear about cruciate retaining knee

Scuderi - direct

1 designs. And there are specific designs that save that  
2 ligament, and a surgical technique, specific femoral and the  
3 tibial components are designed to accommodate the  
4 preservation of the posterior cruciate ligament and allow  
5 certain motions of the knee joint.

6 In contrast, the school of thought that we  
7 actually follow is the posterior cruciate substituting  
8 design. In that particular case, we sacrifice or remove the  
9 posterior cruciate ligament that is in the middle of that  
10 knee joint, and substitute for it the spine-cam mechanism.

11 As you can see on the models here that I have,  
12 the implants, there is a post in the center of the knee  
13 joint. It is a projection, coming up. There is a cam, this  
14 little bar, that is between the femoral condyles. It is  
15 that interaction and that articulation -- and I will show  
16 you from the back because you can see it a little bit  
17 better. As the knee flexes, it engages that tibial spine,  
18 rides down, and you can see, I cannot move that knee in a  
19 posterior direction because that post is helping me. That  
20 post also helps guide the motion of the knee.

21 As I mentioned earlier, the motion of the knee  
22 joint is a complex motion. It's not a hinge joint, if you  
23 think of a door opening and closing. So it actually flexes,  
24 rolls back, and then it rotates.

25 That is describing the geometry of the

Scuderi - direct

:00:55 1 articulate surface, the geometry of the condyles, as well as  
:00:58 2 the spine-cam mechanism. This post in the middle of the  
:01:02 3 joint and that bar that is in between called the cam, that  
:01:05 4 is what is guiding that motion as the knee flexes.

:01:08 5 That is the basic differences between a CR and a  
:01:13 6 PS knee design.

:01:14 7 Q. Does the spine-cam mechanism that you described and  
:01:18 8 showed to His Honor provide the stability that the posterior  
:01:24 9 cruciate ligament is intended to provide?

:01:26 10 A. Yes. Again, that's why we use the term substituting  
:01:29 11 design. It substitutes for the posterior cruciate ligament.

:01:33 12 Q. Now, I would like to have you discuss in a little more  
:01:41 13 detail the femoral component and actually how the femoral  
:01:47 14 component is used in conjunction with the femur. How is it  
:01:52 15 actually used during surgery?

:01:56 16 A. So as I mentioned earlier, the femoral component is  
:01:59 17 what we place on the end of the thigh bone. Again, with  
:02:04 18 precision instruments, we resect -- it's actually resected,  
:02:08 19 about a half an inch of bone all around. So I have to make,  
:02:12 20 if we look at the internal geometry of the component, I need  
:02:15 21 to make cuts very similar to this. What I need to do  
:02:20 22 interoperatively is measure the size of the femur, the shape  
:02:23 23 of the femur, resect the bone at the appropriate levels, at  
:02:27 24 the appropriate angles, to place this component on, to  
:02:29 25 restore the alignment of the knee joint. So this becomes

Scuderi - direct

:02:32 1 your -- this is your new knee. But it has to be placed in  
:02:36 2 the right position with the rest of the anatomy. And that  
:02:41 3 is very critical because we have multiple sizes. It's not  
:02:44 4 one size fits all. We do have to make interoperative  
:02:47 5 measurements to get these knee implants in place.

:02:50 6 Q. Let's move off the anatomy and go to another subject.  
:02:57 7 When did you first become a consultant to Zimmer?

:03:01 8 A. In 1994.

:03:02 9 Q. What is a developer surgeon in knee implant  
:03:11 10 developments?

:03:12 11 A. So a development surgeon is one that works with the  
:03:19 12 engineers, works with the marketing group. It's, again, a  
:03:25 13 surgeon who is working on new designs and development of new  
:03:28 14 implants and products.

:03:29 15 Q. What types of projects have you worked on for Zimmer  
:03:34 16 as a developer surgeon?

:03:36 17 A. I have worked on many projects with Zimmer. The LPS  
:03:41 18 project, the LPS Flex, fixed and mobile-bearing. The  
:03:46 19 patellar femoral, the LCK, which is the revision system, and  
:03:49 20 I am currently on their new knee system. I have also worked  
:03:52 21 on numerous instrument systems with them, which are the  
:03:56 22 devices that we use to prepare the bone.

:03:58 23 Q. Do you recognize the name NexGen?

:04:02 24 A. Yes, I do.

:04:03 25 Q. What is the name NexGen?

Scuderi - direct

:04:04 1 A. NexGen is a knee system that Zimmer markets their  
:04:11 2 implant, their knee implant system.

:04:13 3 Q. I would like to return for just a moment to ISK. What  
:04:30 4 is ISK best known for?

:04:33 5 A. As I mentioned earlier, ISK is a group of  
:04:36 6 internationally known surgeons who are known for knee  
:04:39 7 surgery.

:04:41 8 Q. People have referred to this before, Dr. Insall was  
:04:45 9 the father, godfather, or the God of these?

:04:49 10 A. Yes. He is the primo -- he was really the, you know,  
:04:53 11 the father of total knee replacement as well as other  
:04:56 12 techniques around the knee.

:04:57 13 Q. Do you know when he first did a posterior stabilized  
:05:03 14 artificial knee implant?

:05:06 15 A. He originally introduced the total condyle design,  
:05:09 16 which is a post-cruciate sacrificing design, about in the  
:05:13 17 1970s. In about 1977, I believe, was when the IB, the  
:05:18 18 Insall-Bernstein prosthesis, was designed and developed.

:05:21 19 Q. Now, could you describe to the Court how the  
:05:32 20 physicians at ISK typically function with each other with  
:05:38 21 regard to knee development projects?

:05:41 22 A. The ISK group, myself, Dr. Insall, Dr. Scott and Dr.  
:05:45 23 Kelly with, we are a very collaborative group. We work  
:05:49 24 very, very closely together, on a regular and daily basis.  
:05:53 25 We would see patients together. Look at each others' cases.

Scuderi - direct

:05:55 1 Look at outcomes. The radiographic analysis. Actually  
:05:58 2 perform surgeries together.

:06:01 3 And in design and development, it was, again,  
:06:03 4 very much shared interactive process. And we would look at  
:06:08 5 the various ideas, concepts, and share all those ideas with  
:06:12 6 each other. We are considered a think tank. We are a  
:06:17 7 research center. We had a fellowship program, training  
:06:19 8 other doctors. Other doctors were coming in to visit us.

:06:22 9 There was a great deal of activity, a great deal  
:06:24 10 of interaction. It was primarily, if not exclusively,  
:06:27 11 centered around surgery of the knee. And in that particular  
:06:29 12 case total knee replacement was our, almost -- it was what  
:06:37 13 we were well known for internationally.

:06:38 14 Q. That was true throughout the 1990s?

:06:41 15 A. Absolutely.

:06:42 16 Q. I would like to discuss the process that is used for  
:06:48 17 knee device development at Zimmer.

:06:54 18 Who is on the development team, in your  
:06:58 19 experience?

:07:00 20 A. I think Dr. Rohr had gone through some of that  
:07:02 21 earlier. I think that, the development team, there are many  
:07:07 22 component parts to that. There are many individuals that  
:07:09 23 are involved. It starts out with brand marketing. It is  
:07:12 24 the design surgeons, also engineers. So it is a good sized  
:07:18 25 group. There is various individuals that are components of



Scuderi - direct

1 that project. I never have really done a project where  
2 there was one or two individuals. Again, it was a very  
3 interactive group, you need to collaborate together and  
4 everyone brought something to the table.

5 Q. Are you using design surgeon and developer surgeon  
6 synonymously?

7 A. Yes, I believe the design surgeon is the developer  
8 surgeon.

9 Q. Could you explain to the Court why in this knee  
10 development process developing surgeons, also design  
11 surgeons, are important? Why are they critical to the  
12 process?

13 A. Design surgeons are very critical to the process,  
14 because we know the pathology of the knee, the physiology of  
15 the knee, the kinematics of the knee, we have the surgical  
16 experience to put devices, implants, total knee replacements  
17 in patients.

18 We need to get them in the proper orientation.  
19 We need to know how they move, how stable they are. It is a  
20 very, very critical component of the entire development  
21 team.

22 These are things that others couldn't do.  
23 Engineers have no surgical experience. They don't know the  
24 anatomy. They don't know how to correct the anatomy. They  
25 don't know how to balance the knee in a surgical patient.

Scuderi - direct

:08:29 1 Q. Now, you used a new word you had not used before,  
:08:34 2 kinematics. Could you just explain what kinematics is?

:08:37 3 A. Kinematics is the movement of the knee joint, the  
:08:40 4 interaction of the knee joint.

:08:41 5 Q. How it interacts with the surrounding components of  
:08:45 6 the knee, the patella, the muscle, the tendons, the  
:08:50 7 ligaments, and so forth?

:08:52 8 A. That's correct.

:08:52 9 Q. Now, have you heard the term consulting surgeon?

:09:00 10 A. Yes.

:09:00 11 Q. Is that something different than a developer or design  
:09:05 12 surgeon?

:09:05 13 A. Yes, it is.

:09:06 14 Q. What is the difference?

:09:09 15 A. A consulting surgeon is one who is brought in later,  
:09:15 16 during the field evaluations, to look at the products that  
:09:18 17 we have developed and we get some feedback from them as to  
:09:21 18 the clinical performance. Developers are also, we have  
:09:26 19 surgeons that further test the product before we go possibly  
:09:29 20 to a full market release.

:09:30 21 Q. And have you and Dr. Scott and Dr. Insall while he was  
:09:35 22 alive been developer surgeons for Zimmer?

:09:37 23 A. Yes, we have.

:09:37 24 Q. And what products -- I think I have asked that and you  
:09:46 25 have answered it already.

Scuderi - direct

:09:47 1 Now, why is it that you and Dr. Scott have been  
:09:52 2 retained to be developer surgeons for Zimmer?

:09:56 3 A. Because of our clinical experience and expertise.

:10:01 4 Q. Now, could you explain a little more what you can do  
:10:08 5 as a developer surgeon that a Zimmer engineer is unable to  
:10:13 6 do?

:10:13 7 A. So as I mentioned briefly earlier, one, we can look at  
:10:21 8 a new implant design, prototype, we come up with ideas on  
:10:26 9 implants designs. We can look at these designs, look at the  
:10:30 10 subtleties of these designs on how they interact in the  
:10:34 11 total knee specifically, looking at the interaction of the  
:10:36 12 femur and the tibia. Are we able to achieve the motion?  
:10:40 13 Does it have the stability?

:10:41 14 We can then go to cadaver surgeries, in which we  
:10:44 15 implant these knees on body parts before we take them to the  
:10:49 16 real world, and again, look at how they fit, how they feel,  
:10:53 17 what is the interaction of the femur on the tibia? What  
:10:56 18 type of motion do we have? Roll back, again, stable  
:10:59 19 (indicating).

:10:59 20 We need to design implants that restore  
:11:03 21 function. And part of that, again, is stability. Stability  
:11:06 22 is very important. We could design many products, but it  
:11:08 23 may be very difficult to implant these. Cadavers at least  
:11:12 24 give us the opportunity with prototypes to put them in, into  
:11:16 25 body parts, look at the movement, the kinematics, and we can

Scuderi - direct

:11:20 1 see very subtle differences in orientation of a component,  
:11:22 2 features of a component, some of the ideas and concepts that  
:11:24 3 we have developed and that have been brought to us, looking  
:11:27 4 for solutions.

:11:28 5 Finally, once we have come up with designs and  
:11:30 6 ideas that we think we are beginning to have a safe product  
:11:35 7 and getting close to the final product, we then go to  
:11:37 8 surgeries and we do surgical implants. We use -- sometimes  
:11:41 9 in the nineties we were able to put prototypes in and look  
:11:44 10 at prototypes, take out those components and put the final  
:11:47 11 components in. But we had the ability at that point to  
:11:49 12 actually put them in patients, look at it and make decisions  
:11:53 13 about features of an implant: Was it performing the way we  
:11:58 14 had anticipated? If not, subtle changes can cause a  
:12:01 15 magnitude of problems. We needed to address those and go on  
:12:04 16 to other prototypes before we got to a final design.

:12:06 17 Q. While we are on these subjects, let me ask you a  
:12:11 18 couple of questions about cadaver studies and the live  
:12:16 19 operation study. Did ISK have at its location a cadaver  
:12:26 20 laboratory?

:12:26 21 A. Yes, we did.

:12:27 22 Q. Did you have an operating suite?

:12:29 23 A. Yes, we did.

:12:30 24 Q. So all of the functions that we are talking about were  
:12:34 25 performed at ISK in New York?

Scuderi - direct

:12:37 1 A. That is correct.

:12:38 2 Q. Let's talk about a cadaver study. Could you sort of  
:12:47 3 bring the Court into a cadaver study that took place in  
:12:51 4 conjunction with the Zimmer products, and explain generally,  
:12:56 5 who is there, what happens, what the developer surgeon's  
:13:01 6 role is, what you are looking for and so forth?

:13:03 7 A. So a cadaver surgery, you know, would start with the  
:13:08 8 ideas and concepts that we had put forth in conjunction with  
:13:12 9 the engineers again, collaborating on prototypes, prototypes  
:13:16 10 that would be brought in by the Zimmer engineers. They  
:13:19 11 would have been mailed or carried in.

:13:20 12 We would then go down to the lab. In the lab  
:13:24 13 there would either be a full body or a body part, being an  
:13:28 14 extremity. Let's say it's a right leg. We as the surgeons  
:13:32 15 would perform the surgery, as we would do in a live  
:13:36 16 scenario, in a real operating room, on the knee, create the  
:13:40 17 arthroscopy and resect the bone, as we normally would in  
:13:43 18 surgery.

:13:44 19 We put the implants in, the new provisional  
:13:47 20 implants. The engineers would be there with us because they  
:13:51 21 want to observe what our findings were. Put the implant in,  
:13:55 22 and then we would take the knee through a range of motion.  
:13:57 23 We want to check for stability, did the articulation fit  
:14:01 24 well, did it dissociate, did we have some instability. Did  
:14:04 25 all of a sudden as we put an implant in -- and I will just

Scuderi - direct

:14:07 1 use these -- was there too much gapping or did the knee  
:14:11 2 start falling off the back? Did we design something wrong?

:14:14 3 So there were problems that may have arisen.  
:14:17 4 The engineers would take the records and the reports and we  
:14:20 5 then would finish the procedure, either we are happy and  
:14:23 6 satisfied and say great, let's move on, or we would say,  
:14:27 7 let's change things.

:14:29 8 Then we would go upstairs, back to the  
:14:31 9 conference room. And we would sit and talk about what our  
:14:34 10 observations were and what changes do we think need to be  
:14:38 11 made.

:14:39 12 That is a typical, you know, cadaver. Present  
:14:44 13 were the design surgeons and the engineers who came over  
:14:47 14 from Zimmer.

:14:48 15 Q. When you say we discussed changes that should be made,  
:14:51 16 does "we" include the design surgeons such as Dr. Insall,  
:14:58 17 Dr. Scott and yourself?

:14:58 18 A. Yes. Again, this is very much a collaborative  
:15:01 19 process. As we went on, Dr. Scott, Dr. Insall, myself, you  
:15:04 20 know, would be there with the engineers, whoever had come  
:15:08 21 over.

:15:08 22 Q. Let's move to the next type of study that you referred  
:15:12 23 to just a few minutes ago, and that was in the operation  
:15:16 24 room.

:15:17 25 A. Right.

Scuderi - direct

:15:17 1 Q. I presume that you did that only if you had a  
:15:23 2 prototype that was satisfactory in the cadaver study. Is  
:15:27 3 that right?

:15:27 4 A. That's correct.

:15:28 5 Q. Now, moving to the operation room, would you again try  
:15:33 6 and beam them up and beam them down into the operation room  
:15:38 7 and sort of describe what was going on?

:15:41 8 A. So in this knee scenario, we would have products that  
:15:46 9 were approaching almost final completion or we felt, we  
:15:49 10 thought we had addressed most of the ideas and concepts that  
:15:52 11 we wanted in the final components. In these particular  
:15:55 12 cases, again, the engineers would come visit, they would  
:15:59 13 bring in component parts. And we would perform live  
:16:05 14 surgery.

:16:05 15 The operating was at ISK. We actually have what  
:16:10 16 is called laminar flow rooms. This is a very clean, sterile  
:16:15 17 environment. We operate in space suits. We had Plexiglass  
:16:18 18 that goes around the room. And only the operating team is  
:16:21 19 at the body. Everything else and the observers are behind  
:16:24 20 the Plexiglass.

:16:25 21 They are garbed, they have scrubs and masks on.  
:16:27 22 But they are behind the Plexiglass. They are about, six to  
:16:32 23 eight feet away from the body.

:16:34 24 We would do the surgery. And again, this was a  
:16:39 25 patient who was going to ultimately have a final component.

Scuderi - direct

1 But we would use the prototypes, place them in the knee and  
2 then look at the motion of the knee. Now, this was, again,  
3 better than a cadaver because we had all the muscles and the  
4 ligaments. It was healthy tissue and we can get a better  
5 feel. And again, based upon our observations, you know, we  
6 could look for any subtle, either problems, or satisfaction,  
7 you know, in those implant designs.

8 So we were right there.

9 The information that we conveyed to the  
10 engineers was based upon, you know, look from six to eight  
11 feet away, see what we have. See how the knee moves. I am  
12 happy. Sometimes we would give them the thumbs up sign and  
13 say, hey, I think we got it. Then afterwards we would take  
14 out the prototypes, finish it with the real implant. Close  
15 the knee. The patient goes to the recovery room.

16 In between cases or at the conclusion of our  
17 operating day, we would then have a meeting and a debriefing  
18 where we would go over the features of our prototypes.

19 Q. Because you and Dr. Scott and Dr. Insall were right  
20 there operating -- by the way, how close would you be to the  
21 knee when you were doing this surgery we are talking about?

22 A. I could get as close as six inches when I am really  
23 looking for some very subtle movement. Again, as we were  
24 looking at specific features, roll-backs, flexion,  
25 impingement of the femur on the poly, we get very, very



Scuderi - direct

:18:10 1 close to that knee joint.

:18:11 2 Q. Would the engineers who were several feet away behind  
:18:14 3 Plexiglass in their own suits be able to see those subtle  
:18:19 4 movements from where they were?

:18:20 5 A. No. They would have to rely on us. We could not get  
:18:22 6 them that close.

:18:23 7 Q. And as a result of observing these subtle movements,  
:18:26 8 did you as developer surgeons arrive at some design concepts  
:18:31 9 to deal with what you were seeing?

:18:32 10 A. Yes. We would come up with, if we needed a solution  
:18:36 11 we would come up with new design ideas, solutions to any  
:18:39 12 problems that would have arisen, and then explain those  
:18:42 13 ideas to the engineers.

:18:44 14 Q. Now, if we could, let's change subjects again, and  
:18:50 15 talk about ISK. Could you describe to the Court what a  
:18:55 16 typical day at ISK was like, particularly in the  
:18:59 17 mid-nineties, the period of time we are talking about?

:19:02 18 A. So a typical day would begin about 7:00, we would,  
:19:06 19 myself, Dr. Insall, Dr. Scott, Doctor Kelly, we would get  
:19:10 20 into the office, have a conference in the morning, about  
:19:13 21 7:30, then we would all head to Dr. Insall's office. He  
:19:17 22 didn't have a desk. And I think Bill Rohr actually  
:19:20 23 mentioned, he had a round table. We would sit around the  
:19:22 24 table, and have a cup of coffee and talk about cases, talk  
:19:26 25 about the surgical schedule for the day. Talk about

Scuderi - direct

1 patients. Look at x-rays. Talk about implant designs.

2 John always had design ideas. We had ideas.

3 And again, as I mentioned about, it was a think tank.

4 That's how our day would start.

5 By 9:00 we would either be heading down for our  
6 first case, the fellows would get the cases prepped for us,  
7 we would usually head down around 8:30, 9:00 or else we went  
8 to clinic. Again, we were together on an hourly and daily  
9 basis.

10 Everything occurred at the ISK Institute. We  
11 have our operating rooms there. We had the lab there. We  
12 had our offices there. We had the research facilities  
13 there.

14 Again, we spent every hour of every day at the  
15 institute.

16 It would be a very interactive event. John and  
17 I would see patients together at the same time. I was the  
18 senior fellow, so I had to be around John all the time.  
19 It's like having a junior associate or a clerk that is with  
20 you all the time, be available to you.

21 I would see patients the same time as John did.  
22 I would operate the same time. I would operate on all  
23 John's cases.

24 So again, we would look at outcomes, we would  
25 look at x-rays, and we would discuss cases. We would be

Scuderi - direct

:20:39 1 happy when we had a great result. There are some  
:20:41 2 interesting patients that had my flexion, or we would talk  
:20:45 3 about problems that we saw. The radiolucent lines as Bill  
:20:49 4 Rohr brought up or some failure, some revision that was  
:20:51 5 coming in from elsewhere, talk about that. Then talk about  
:20:54 6 design ideas.

:20:57 7 So again, it was very much interactive. And  
:20:59 8 John and I were very close. Norm was a part of that, too.  
:21:02 9 Norm was right there. My office was just slightly down the  
:21:05 10 hall from John's. Norm's was right next-door. I think Norm  
:21:09 11 was separated by five or six feet.

:21:10 12 Again, lunchtime came, we had to have lunch with  
:21:13 13 John, we never left the building until John left. For me it  
:21:17 14 was tough, John lived across the street. I lived in Long  
:21:19 15 Island, so I had to drive 20 miles to go home at 7, 8:00 at  
:21:23 16 night.

:21:23 17 We stayed with John, because that was very  
:21:26 18 important. To me, it was another vast experience for me.  
:21:29 19 He was my mentor. I appreciate that.

:21:32 20 Q. These discussions that you had had, these  
:21:36 21 conversations, in the morning, 7:30, as well as throughout  
:21:41 22 the day, was it the practice of the surgeons at ISK to make  
:21:47 23 notes and keep records of what was discussed at these  
:21:50 24 meetings?

:21:51 25 A. No, we did not.

Scuderi - direct

:21:53 1 Q. And why is that the case?

:21:55 2 A. Well, you know, as I mentioned, we were always  
:21:57 3 together. We shared the same ideas. Lively discussion. We  
:22:02 4 had no reason to keep records. We knew what each other was  
:22:05 5 thinking. Sometimes John would start a sentence we could  
:22:10 6 finish it or Norm would start a sentence and John would  
:22:13 7 finish it. We were that close.

:22:14 8 There was no reason at this point for us to keep  
:22:16 9 any records. We felt that we were sharing all our  
:22:18 10 information. It was very much a collaborative process,  
:22:22 11 through anything that we did, we would collaborate on cases,  
:22:24 12 collaborate on surgery, collaborate on implant design.  
:22:27 13 Everything that we did was a collaboration.

:22:29 14 Q. Is the recordkeeping process different today than it  
:22:32 15 was in the 1990s?

:22:34 16 A. Yes.

:22:35 17 Q. When did it change?

:22:42 18 A. It changed several years ago, about 2007, 2008, 2009.

:22:55 19 MR. FRIEDMAN: Your Honor, I want to use an  
:22:56 20 exhibit at this point. I understand there is an objection  
:22:59 21 to that exhibit.

:23:00 22 MR. HALES: Your Honor, I think the objection is  
:23:02 23 relevance. If I understand where Mr. Friedman is heading  
:23:04 24 with this, as Dr. Scuderi just testified, this is a change  
:23:08 25 that happened in about 2007. There is no relevance to

Scuderi - direct

:23:11 1 anything in 2007.

:23:13 2 THE COURT: So this is post the period of the  
:23:14 3 issuance of the patent.

:23:17 4 MR. HALES: By seven or eight years.

:23:20 5 MR. FRIEDMAN: I can explain what the relevance  
:23:22 6 is, Your Honor.

:23:22 7 THE COURT: Go ahead.

:23:23 8 MR. FRIEDMAN: From the opening, and as you will  
:23:26 9 hear from the testimony, Zimmer is going to be making a very  
:23:31 10 substantial point that there is an absence of minutes,  
:23:37 11 records, something reporting who said what when, who was the  
:23:45 12 first one to do it. "We see nothing in those minutes, do  
:23:48 13 we, saying who was the first one?"

:23:50 14 One of the pages of this document is going to  
:23:53 15 describe the note-taking practices that existed prior to  
:24:00 16 2007.

:24:01 17 THE COURT: Back during the relevant time frame.

:24:04 18 MR. FRIEDMAN: That's correct. This witness is  
:24:06 19 going to be able to look at that exhibit and say, yes, just  
:24:11 20 as that exhibit says, it's a Zimmer document, those are the  
:24:15 21 practices that were followed for note-taking or  
:24:18 22 minute-taking back in the period of time that's relevant to  
:24:21 23 us.

:24:23 24 THE COURT: Counsel.

:24:24 25 MR. HALES: Your Honor, in a sense this is a

Scuderi - direct

1 little like a subsequent remedial measure. But in any  
2 event -- well, the relevancy is still not there. There are  
3 records from the relevant time period.

4 THE COURT: I disagree with you, to the extent  
5 that internal aspects of the document -- maybe not the  
6 overall document. I take your point. But you listened just  
7 as I did to your opponents explanation as to a particular  
8 area of the document, part of the document he wishes to call  
9 out. I am going to rule that -- and this is subject to me  
10 changing my mind once I see the document. I haven't seen it  
11 yet. But at this point, I am going to permit it.

12 I don't agree with your analogy with remedial  
13 measures. At least at this point, I don't see the analogy.  
14 I am going to let it in right now, or let him use it.

15 MR. HALES: Thank you.

16 BY MR. FRIEDMAN:

17 Q. Could you turn to PTX-338?

18 Could you put that up on the screen, please.

19 I am particularly interested starting with the  
20 page that says, Capturing your development contributions.

21 THE COURT: 338, counsel?

22 MR. FRIEDMAN: Yes.

23 BY MR. FRIEDMAN:

24 Q. Have you seen this document before?

25 A. Yes, I have.

Scuderi - direct

:25:58 1 Q. What is it?

:26:00 2 A. This is a booklet that was given to the new  
:26:05 3 development team as to how our contributions should be  
:26:10 4 recorded with the new project.

:26:13 5 Q. Could we turn to the next page of that exhibit, which  
:26:18 6 has at the bottom 24105. Just enlarge it, if you would, for  
:26:24 7 me.

:26:26 8 You see that it's entitled Historical  
:26:29 9 Perspective?

:26:31 10 A. Yes.

:26:31 11 Q. And there is a section, No Formal Process. Does this  
:26:40 12 document describe the manner in which notes were kept by  
:26:47 13 Zimmer and by you prior to 2007 regarding designs and those  
:26:55 14 kinds of things?

:26:56 15 A. Yes.

:26:57 16 Q. All right. And how is it different today?

:27:05 17 A. Today, we, at the design and development meetings, we  
:27:09 18 are handed the blue books, which is mentioned on the first  
:27:12 19 page of the document. And in that we are to write down our  
:27:16 20 ideas, our thoughts, our concepts. And that's collected at  
:27:19 21 the end of the development meetings.

:27:20 22 Q. And in this section where it talks about no formal  
:27:26 23 process and there are five items that are listed, is that  
:27:30 24 your understanding of the practice that was followed in the  
:27:33 25 1990s with regard to the knee development projects for

Scuderi - direct

:27:37 1 Zimmer that you were involved in?

:27:41 2 A. Yes.

:27:42 3 MR. FRIEDMAN: We move this into evidence.

:27:44 4 THE COURT: It is in. I am going to stand by  
:27:45 5 the ruling. I believe it is relevant.

:27:48 6 MR. FRIEDMAN: Thank you, Your Honor.

:27:49 7 BY MR. FRIEDMAN:

:27:50 8 Q. Now, let's discuss actually how ISK and the  
:28:02 9 developers --

:28:03 10 THE COURT: Counsel, since you are going to a  
:28:07 11 different subject, let's take a short stretch.

:28:11 12 MR. FRIEDMAN: How long?

:28:12 13 THE COURT: Long enough for you, if you need to,  
:28:15 14 to go to a facility.

:28:20 15 (Recess taken.)

:37:36 16 THE COURT: Please take your seats, and let's  
:37:39 17 continue.

:37:45 18 BY MR. FRIEDMAN:

:37:46 19 Q. I would like to just address the ways in which ISK  
:37:51 20 communicated with the Zimmer engineers. Did all of the ISK  
:37:55 21 surgeons communicate with Zimmer engineers from time to  
:38:00 22 time?

:38:00 23 A. From time to time, yes, we did.

:38:03 24 Q. How was it principally done?

:38:05 25 A. It was principally done through Dr. Insall. He was



Scuderi - direct

:38:11 1 the senior partner in the group. And he communicated  
:38:14 2 directly with them.

:38:18 3 Q. How would the process work that he would communicate  
:38:21 4 the collective contributions of the ISK group?

:38:26 5 A. After meetings that we had internally, myself, Dr.  
:38:29 6 Scott, Dr. Insall, with design ideas and concepts, just to  
:38:34 7 make it easier from an organizational point of view, Dr.  
:38:37 8 Insall was the primary spokesperson, he would communicate  
:38:41 9 with the Zimmer engineers, the principals, such as Bill  
:38:44 10 Rohr, as you heard earlier, either directly, face to face,  
:38:47 11 phone conversations, even letters, sometimes a fax.

:38:51 12 Q. Was he the point man for the group?

:38:54 13 A. Yes.

:38:55 14 Q. Now, you heard Dr. Rohr testify about some problems  
:39:00 15 that existed in the NexGen products in the early 1990s.

:39:07 16 Correct?

:39:07 17 A. Yes, I did.

:39:09 18 Q. And they led to the development of the LPS?

:39:12 19 A. Yes.

:39:12 20 Q. Could you explain what ISK's involvement is, what your  
:39:20 21 involvement was in identifying those problems?

:39:27 22 A. The ISK group were all involved in the process. Dr.  
:39:32 23 Insall, Dr. Scott and myself had noted on some Nex-Gen PS  
:39:37 24 x-rays that there were radiolucent lines. Dr. Insall was  
:39:40 25 concerned, he had seen this type of finding on a predicate

Scuderi - direct

1 device, and was concerned about early failure.

2 We did a --

3 Q. What does radiolucent lines mean?

4 A. It's a little black-line underneath the implant. So  
5 if you had a tibial tray sitting on the bone, it means that  
6 the bone is not growing in or the cement is not bonding to  
7 the tray. That means it's not well fixed. What happens  
8 then is, as the knee moves, maybe there is some rocking and  
9 it can come loose, separate from the bone. There would be  
10 some early failure.

11 So these were observations that concerned Dr.  
12 Insall, from his past experience. He brought this to  
13 Zimmer's attention.

14 Q. What was your role specifically in collecting  
15 information relating to these problems?

16 A. So once we identified this problem, we had a meeting  
17 with the Zimmer management and engineers. And my role was  
18 to look at all the x-rays from all the surgeons. So  
19 surgeons from around the country who had used the NexGen PS  
20 had sent x-rays to me. And I was also tasked for those that  
21 did not to travel around the country, to sit in their office  
22 and look at all the x-rays, to look specifically for these  
23 x-ray radiographic findings.

24 Q. And what was Dr. Scott's involvement in collecting and  
25 analyzing information relating to the NexGen PS?

Scuderi - direct

:41:08 1 A. So once again, once we identified the issues and the  
:41:11 2 x-rays were brought in, again, Dr. Insall, Dr. Scott and  
:41:15 3 myself, along with Bill Rohr and others, we looked at the  
:41:19 4 x-rays, and made some decisions as to what the direction  
:41:23 5 would be.

:41:23 6 Q. How were these problems that you uncovered  
:41:29 7 communicated to Zimmer?

:41:31 8 A. They were communicated directly to Zimmer, Bill Rohr  
:41:34 9 was, you know, part of that process, as he mentioned  
:41:38 10 earlier. Dr. Insall communicated, we had actually meetings  
:41:44 11 about that and further development changes.

:41:46 12 Q. What happened after these problems were communicated  
:41:48 13 to Zimmer and Zimmer understood it had a problem?

:41:51 14 A. So as Bill Rohr testified, the NexGen PS was then  
:41:56 15 modified to the -- or redesigned, actually, to the LPS, the  
:42:01 16 Legacy posterior stabilized knee.

:42:03 17 Q. Let's discuss how ISK worked with Zimmer on the  
:42:08 18 development of the LPS project.

:42:10 19 In fact, let me ask that question. How did ISK  
:42:15 20 work with Zimmer with regard to the creation of the LPS?

:42:19 21 A. So the LPS project was done exclusively at Zimmer as  
:42:29 22 the design surgeons, Dr. Insall, again --

:42:31 23 Q. I am sorry. You said done at Zimmer's design as  
:42:36 24 surgeons?

:42:37 25 A. At ISK. Yes. I am sorry if I said that.

Scuderi - direct

:42:39 1 Q. I am sorry.

:42:40 2 A. That's okay. So, again, it was done with the design  
:42:44 3 surgeons at the ISK Institute, myself, Dr. Insall, Dr. Scott  
:42:47 4 and Dr. Kelly, working with Dr. Rohr in a very rapid time we  
:42:54 5 were able to redesign the NexGen PS to the LPS.

:42:58 6 Q. How long did it take to do that?

:43:01 7 A. I think Bill Rohr actually said it was about 14 weeks.  
:43:04 8 I was going to say about three or four months. That fits  
:43:06 9 within that same time frame. It was a very rapid process.

:43:09 10 Q. During that period of time was Dr. Rohr at ISK?

:43:14 11 A. Bill almost moved in. I mean, he came over to New  
:43:18 12 York, and relocated there for a while. He was there on a  
:43:22 13 weekly basis, if not daily at times. This was a very  
:43:25 14 important project. It had to get accomplished quickly. I  
:43:29 15 think Dr. Rohr testified to that fact. It was a problem  
:43:32 16 that needed to be resolved quickly.

:43:33 17 Q. In developing the designs for the LPS, who did you  
:43:39 18 work principally with?

:43:42 19 A. I worked, you know, with Dr. Insall, Dr. Scott, and  
:43:46 20 Dr. Rohr. But as I mentioned earlier, I spent almost all my  
:43:50 21 daily time with Dr. Insall. I worked very closely with Dr.  
:43:55 22 Insall throughout the process.

:43:57 23 Q. Did Dr. Scott during that time develop a social  
:44:00 24 relationship with Dr. Rohr?

:44:02 25 A. Yes. I mean, they were very close colleagues. They

Scuderi - direct

:44:06 1 had really developed a very good friendship. Bill actually  
:44:10 2 moved is, as I said, to New York. And Norm and Bill would  
:44:14 3 go to dinner, socialize after hours.

:44:16 4 Q. Did you have a social relationship with Dr. Rohr like  
:44:19 5 that?

:44:19 6 A. No, I did not.

:44:20 7 Q. How frequently would you see or speak with Dr. Rohr  
:44:25 8 while he was residing at ISK?

:44:27 9 A. Whenever he was in the institute, in the office, in  
:44:32 10 the building, even in surgery, Dr. Rohr would come to the  
:44:35 11 operating room to look at various measurements or prototype  
:44:39 12 ideas and designs.

:44:40 13 Q. And so, just explain why it was you worked closer with  
:44:44 14 Dr. Insall?

:44:46 15 A. You know, again, as I mentioned and testified earlier,  
:44:49 16 Dr. Insall and I were tied at the knee. Everything that Dr.  
:44:52 17 Insall did I was with him during that process. Norm and  
:44:56 18 Bill were contemporaries. They developed a friendship and  
:45:00 19 Bill testified to that, he helped through the process. I  
:45:06 20 had a relationship with Dr. Rohr. I had a relationship with  
:45:09 21 Dr. Scott. When it comes down to doing work sometimes, you  
:45:13 22 got to spend it with Dr. Insall. You are in that operating  
:45:18 23 room and doing everything I could to help him.

:45:21 24 Q. Dr. Rohr had indicated that the LPS was designed in  
:45:27 25 approximately 14 weeks. Is that an unusual period of time

Scuderi - direct

:45:32 1 for the development of such a complex device?

:45:35 2 A. As I mentioned earlier, that was a very rapid process.

:45:37 3 That was a very quick design.

:45:39 4 Q. How is it that you and Zimmer together were able to

:45:43 5 design that so quickly?

:45:46 6 A. I think because Zimmer and the ISK group were totally

:45:49 7 committed to getting this done. It was the way the ISK

:45:52 8 group was structured, with the design surgeons all being in

:45:57 9 one location, we had Bill Rohr there working with us. We

:46:03 10 had the cadaver lab. We had surgery. Bill had come up with

:46:05 11 the rapid prototype model, which made it easier for us to

:46:10 12 get prototypes quickly.

:46:10 13 And that was how close that group was. Again,

:46:14 14 it was proximity with all, everybody basically in one room,

:46:17 15 one building, working hard to get this project done quickly.

:46:20 16 Q. Now, do you recognize the term High-Flex, or High-Flex

:46:26 17 Knee?

:46:26 18 A. Yes.

:46:26 19 Q. Can you explain what you mean by High-Flex Knee?

:46:31 20 A. Original knee designs back in the 1990s were designed

:46:37 21 for only about 120, 125 degrees of flexion. They were not

:46:42 22 for, you know, full flexion of the knee joint. So that was

:46:47 23 the primary direction these were going at that point in

:46:52 24 time.

:46:52 25 Q. With a High-Flex knee, what was the flexion goal?

Scuderi - direct

:47:01 1 A. Our goal was to get full flexion for those patients  
:47:04 2 that had motion beyond 120, 125 degrees. You know, it was  
:47:08 3 known to us that there are certain groups of patients,  
:47:13 4 certain individuals, certain ethnic groups, Bill Rohr  
:47:18 5 mentioned the Asian population, who had a high degree of  
:47:21 6 flexion, where it went well beyond 135, we are looking at  
:47:24 7 145, 155, 170 degrees of flexion. There was no implant at  
:47:28 8 that point that was designed specifically to achieve that  
:47:31 9 degree of flexion.

:47:32 10 It was a knee, and with a high-flexion knee  
:47:37 11 concept, it was to try to get a knee that reached some of  
:47:39 12 those limits.

:47:40 13 Q. Was the LPS a High-Flex knee?

:47:44 14 A. No, it was not.

:47:44 15 Q. Why is that important?

:47:47 16 A. Well, because that implant's design again was only for  
:47:50 17 120 to 125 degrees of flexion.

:47:53 18 Q. Now, do you understand High-Flex now, and certainly  
:47:59 19 it's important in this case to include High-Flex fixed and  
:48:04 20 High-Flex mobile?

:48:05 21 A. Yes.

:48:05 22 Q. Let's talk about the Asian market. What did you learn  
:48:10 23 about the Asian market and the need for greater flexion and  
:48:15 24 when and how did you learn it?

:48:17 25 A. Early in 1995, after Dr. Insall came back from a trip

Scuderi - direct

:48:24 1 in Japan, he was making comments to us that these patients  
:48:30 2 had a high degree of flexion. For social and cultural  
:48:35 3 reasons, patients needed to achieve motion well beyond 125  
:48:39 4 degrees. For instance, the Japanese population, they stay  
:48:43 5 in a position where they sit back on their heels for tea or  
:48:46 6 for some of their religious activities.

:48:48 7 They needed to get that motion back, if they had  
:48:52 8 arthritis and a total knee replacement. Implants were not  
:48:56 9 designed for that.

:48:57 10 That generated a lot of discussion. And as Bill  
:49:00 11 Rohr said, his trip to Korea, where he was seeing that for  
:49:04 12 reasons of patients not getting their motion back, they  
:49:07 13 didn't want their total knee replacement. They became a  
:49:09 14 topic of discussion early in 1995 with Dr. Insall, Dr. Scott  
:49:13 15 and myself.

:49:14 16 Q. At that time in early 1995, had Zimmer decided to  
:49:18 17 create a high-flexion product?

:49:20 18 A. No, they had not.

:49:21 19 Q. Now, you just made reference to discussions that you  
:49:27 20 had with Dr. Insall and Dr. Scott regarding the knee for a  
:49:35 21 High-Flex product.

:49:36 22 I want to draw your attention to April of 1995.  
:49:42 23 Do you remember a specific discussion that you had with Dr.  
:49:45 24 Scott and Insall in April of 1995 regarding the design for a  
:49:53 25 High-Flex knee?



Scuderi - direct

:49:54 1 A. Yes. In April of 1995, Dr. Insall, Dr. Scott and  
:50:02 2 myself, even Dr. Kelly was involved in that discussion, were  
:50:06 3 talking about the High-Flex knee, the potential, can we get  
:50:09 4 a full flexion knee. What can we do. What design concepts,  
:50:13 5 what design ideas could we achieve?

:50:17 6 You know, around John's table, as I mentioned  
:50:21 7 earlier, we were meeting 7:00 in the morning. I remember,  
:50:24 8 it was one day, we started discussing different design  
:50:29 9 ideas. We came up with a few. There were a few ideas that  
:50:32 10 we came up with on that particular conversation.

:50:34 11 Q. Would you call that a brainstorming session?

:50:38 12 A. It was absolutely a brainstorming session.

:50:40 13 Q. During that brainstorming session, did different  
:50:44 14 participants make drawings, doodles, and the like?

:50:47 15 A. So we had a pad on the table and were drawing out, you  
:50:51 16 know, various ideas, concepts, thoughts on how we could  
:50:56 17 achieve high flexion or at least an implant that achieves  
:50:59 18 high flexion. So, remember, the concept of high flexion is  
:51:02 19 that the patient had good motion, had motion that got to 160  
:51:06 20 degrees, 170 degrees.

:51:07 21 And it was a matter, can we design an implant  
:51:11 22 that safely allows the patient to maintain that motion.  
:51:15 23 That is where the design concepts came from.

:51:17 24 Q. Do you recall any specific design ideas that were  
:51:20 25 discussed, that arose during that brainstorming session?

Scuderi - direct

:51:24 1 A. I specifically remember at least three ideas that we  
:51:26 2 came up with during that brainstorming. One was a modular  
:51:31 3 augment to the posterior condyle. A second was a  
:51:36 4 non-modular augment. And a third was actually changing the  
:51:40 5 flexion position of the femoral component. So instead of  
:51:44 6 putting it straight on we could actually give it a little  
:51:47 7 bit of a tilt and tuck in the posterior condyle.

:51:50 8 Q. And you have specific recollection of discussing those  
:51:53 9 three designs during that meeting?

:51:55 10 A. Absolutely.

:51:55 11 Q. Now, let's take them one by one, and explain to the  
:52:01 12 Court what you mean by them?

:52:03 13 Let's first talk about the module -- or the  
:52:07 14 augment. Perhaps you can use the devices that are in front  
:52:14 15 of you to illustrate that.

:52:17 16 A. So we were looking at the predicate device, the  
:52:21 17 original implants, that had no augmentation on the back.  
:52:24 18 This is actually an augmented implant. We were looking at  
:52:29 19 extending the posterior condyle. One of the issues was we  
:52:32 20 needed to create another articulation in the posterior  
:52:35 21 aspect of the knee, and let's just call it the posterior  
:52:40 22 superior aspect of the femoral component.

:52:42 23 For the standard implant, the problem was that,  
:52:44 24 as the knee flexed, it was a very sharp edge. And anything  
:52:48 25 beyond 125 degrees, that edge would dig into the

Scuderi - direct

1 polyethylene. And that would cause damage. If you had  
2 damage to the polyethylene, it creates debris, debris  
3 creates the osteolysis Bill Rohr testified about yesterday  
4 and that could lead to failure. What we needed to do was  
5 create another articulation, posterior superior  
6 articulation, so as the knee flexed, again, we made nice  
7 smooth contact in that moment as we got beyond the 125  
8 degrees.

9 One thought that came up was that in our  
10 revision cases, we were adding modular augments.

11 Q. What is your revision case?

12 A. It is a re-do. When an implant fails, you take out  
13 the old parts, you got to put some new parts in. When you  
14 put the new matters in, you lose bone, because obviously,  
15 it's probably cemented in as you take it out, the osteolysis  
16 Bill Rohr talked about, that is loss of bone.

17 We have an illustration up there that may help  
18 us a little bit.

19 But we had thought that because in our revision  
20 system we had posterior augments of five millimeters, why  
21 not add that and you get to the back. If you look at Figure  
22 4 and 5, that is showing you an augmentation, module of  
23 augmentation for the posterior condyle.

24 So what we thought of is let's take that little  
25 piece and let's put it on the back of the femur.

Scuderi - direct

:54:18 1 So we took this little piece and we put it on  
:54:22 2 the back of the femur. As you see here, can we extended  
:54:26 3 that posterior condyle? This drawing, Figure 7, actually  
:54:29 4 shows that. Why did we come up with this piece? Because we  
:54:33 5 had that piece available to us. It was in the revision set.

:54:36 6 Now, it wasn't designed for that. We would have  
:54:38 7 to do some other changes to it. But it was basically the  
:54:42 8 five millimeters that we had initially thought about.

:54:46 9 So that was the concept of modularity. It was  
:54:50 10 greatly available, and we thought that with some patients we  
:54:54 11 could incorporate that into the high-flexion knee.

:54:57 12 Q. Let's go to the second idea that you remember being  
:55:00 13 discussed, the second design idea, which was non- -- I think  
:55:04 14 you said non-modular augmentation?

:55:07 15 A. Correct.

:55:07 16 Q. With what does that mean?

:55:09 17 A. In that particular case, instead of adding a piece,  
:55:11 18 because then we would have to have issues of interfaces, how  
:55:14 19 are we going to fix it, are we going to cement it, screw it  
:55:18 20 in, and what is the transition going to be between the  
:55:21 21 modular augment and the femoral component, in contrast what  
:55:23 22 we did, actually, that came out in the final design, is we  
:55:26 23 went non-modular. We just extended the posterior condyle,  
:55:30 24 adding more metal to it.

:55:31 25 That meant we did have to resect more bone.

Scuderi - direct

1 Even with the modular component we would have to take an  
2 additional five millimeters of bone. In this particular  
3 case, we elected, one concept that came up was making it  
4 non-modular, just building up the back of a condyle. We had  
5 done that before for a different reason. Again, it was for  
6 revision, re-do cases, again with bone loss. For some of  
7 the concepts that we thought of during revision surgery  
8 where we had bone loss and we wanted to reestablish the  
9 anatomy of the knee, we want to try to get, again, the shape  
10 of the femur, and we had to deal with defects and revision  
11 surgery, we took some of those concepts and we applied it to  
12 the High-Flex knee. It did need various adaptations because  
13 those augments and that buildup was for stability. That was  
14 again to restore the anatomy of the knee, to provide  
15 stability and revision arthroplasty.

16 From a very technical point, again, it was can  
17 we get those ligaments balanced in the revision. And you  
18 have to build it up some way. That's where that came up.  
19 But in the High-Flex knee, our goal was again to try to  
20 restore the posterior condyle and give an articulation so as  
21 that knee bends, we had a smooth transition, no digging in,  
22 as you can see, it just prevented another articulation.  
23 That was the non-modular idea that we had come up with at  
24 that time.

25 Q. Was one of the advantages of the non-modular idea that

Scuderi - direct

:57:00 1 you would have to remove less bone from the bottom of the  
:57:03 2 femur?

:57:04 3 A. You know, ultimately, that's what it came to. But at  
:57:07 4 that point we were deciding how much bone do we have to  
:57:09 5 take. In the total knee replacement, you want to try to  
:57:12 6 preserve bone. Bone is your building block. The more bone  
:57:15 7 you take, that is problematic to the patient if you have to  
:57:18 8 come back for a re-do and revision because you have to build  
:57:21 9 that up.

:57:21 10 We really hadn't decided exactly how much bone  
:57:24 11 needed to be taken at that time back in April. We would  
:57:29 12 still think five millimeters because that was the size of  
:57:32 13 our modular augment. But we, you know, over time decided  
:57:37 14 how much we really thought was going to be acceptable, and  
:57:39 15 how can we build up that posterior superior articulation.  
:57:43 16 So that was part of the collaborative process for months to  
:57:46 17 follow.

:57:48 18 Q. Can I have DTX-110, please?

:57:51 19 I don't know if you are going to have to turn to  
:57:56 20 it in your book. Just enlarge it a little bit, if you  
:58:00 21 would.

:58:00 22 You recognize this document, and the focus of  
:58:05 23 depositions and testimony and so forth. Correct?

:58:09 24 A. Yes.

:58:10 25 Q. When did you first see this document, if you recall?

Scuderi - direct

:58:13 1 A. Well, this particular document, you know, I saw during  
:58:18 2 our discovery of materials.

:58:20 3 Q. Now, this is not one of the drawings that was made  
:58:26 4 during the brainstorming session that you specifically  
:58:30 5 recall in April of 1995. Correct?

:58:32 6 A. Correct.

:58:33 7 Q. But does this drawing reflect the same design idea or  
:58:39 8 concept that you discussed during your meeting with Dr.  
:58:44 9 Insall and Dr. Scott in April of 1995?

:58:47 10 A. Yes, it is. This is a very similar drawing that we  
:58:49 11 had in our discussions.

:58:50 12 Q. And the concept that is being addressed here that was  
:58:54 13 discussed is what?

:58:57 14 A. Again, this is a buildup of the posterior condyle of  
:59:00 15 the femur. And again, it shows five to six millimeters,  
:59:06 16 question mark.

:59:07 17 Q. Do you know why Dr. Insall sent this to Ms. Beckman  
:59:13 18 following your brainstorming session?

:59:18 19 A. I am not sure the exact intent. But I would assume --

:59:22 20 MR. HALES: Objection to lack of foundation.

:59:23 21 THE COURT: Yes. We are going to see if you can  
:59:27 22 establish a foundation. Otherwise, it's speculation.

:59:29 23 BY MR. FRIEDMAN:

:59:29 24 Q. You had testified earlier that Dr. Insall was the  
:59:32 25 point person for conveying information to Zimmer?

Scuderi - direct

:59:35 1 A. That's correct.

:59:35 2 Q. Do you know why it was that it was Dr. Insall who  
:59:38 3 communicated this to Ms. Beckman?

:59:43 4 MR. HALES: Dr. Scuderi said he had never seen  
:59:46 5 the document until litigation. So I still don't think there  
:59:49 6 is foundation established for this.

:59:50 7 THE COURT: What do you say to that, counsel?

:59:52 8 MR. FRIEDMAN: I am saying there is a  
:59:54 9 foundation. The fact he didn't see it until the litigation  
:59:56 10 started doesn't prevent him from testifying as he would that  
:00:03 11 it was -- that was Dr. Insall's role as the point man to  
:00:07 12 collect the contributions made by the other surgeons and to  
:00:12 13 communicate them to Zimmer. That is precisely what he said.

:00:16 14 THE COURT: I understand that was Dr. Insall's  
:00:18 15 role. Still, I think you need to move on.

:00:25 16 MR. FRIEDMAN: I will move on.

:00:27 17 BY MR. FRIEDMAN:

:00:27 18 Q. Can I have up the '729 patent, please, DTX-1. Claim  
:00:43 19 1.

:00:43 20 If you can enlarge Claim 1.

:00:50 21 Now, is the concept for thickening of the  
:00:59 22 condyles to extend the femoral articulating surface to allow  
:01:04 23 for high flexion found in Claim 1 of the patent?

:01:08 24 A. Yes, it is.

:01:10 25 MR. HALES: Your Honor, I am sorry. I have an



Scuderi - direct

:01:11 1 objection again. Because I think what Dr. Scuderi is being  
:01:15 2 asked to do now is provide expert testimony effectively  
:01:18 3 regarding the scope of the claims.

:01:19 4 THE COURT: Is that the import of this line of  
:01:21 5 questioning?

:01:23 6 MR. FRIEDMAN: No, this is not claim  
:01:25 7 interpretation or claim instruction. We are going to link  
:01:30 8 up, as we are required to do, the specific contributions,  
:01:34 9 design contributions, that were made to language in the  
:01:38 10 claims.

:01:39 11 THE COURT: Objection overruled. We will have  
:01:43 12 an expert. I am not going to permit cumulative testimony,  
:01:47 13 expert testimony. I think everyone understands the Court's  
:01:49 14 position on that. I think counsel has just satisfied me of  
:01:55 15 a proper intent for this testimony.

:01:56 16 MR. FRIEDMAN: Thank you.

:01:58 17 BY MR. FRIEDMAN:

:01:58 18 Q. You have read this patent before. Correct?

:02:02 19 A. Yes.

:02:03 20 Q. Probably several times?

:02:06 21 A. Several times.

:02:07 22 Q. Could you show the Court where in Claim 1 the specific  
:02:14 23 idea for changing the posterior condyle which you have  
:02:18 24 discussed with Dr. Scott and Insall during that  
:02:22 25 brainstorming session appears?

Scuderi - direct

:02:26 1 A. So in this particular paragraph, it says a posterior  
:02:46 2 condyle extending posteriorly from the distal condyle to  
:02:49 3 form a posterior articular surface, and a superior condyle  
:02:53 4 extending superiorly from the distal condyle to form a  
:02:57 5 superior articular surface, the distal condyles, the  
:03:01 6 posterior condyles, and the superior condyle defining a  
:03:05 7 smooth articular surface extending around the exterior of  
:03:08 8 the implant.

:03:09 9 BY MR. FRIEDMAN:

:03:09 10 Q. You understand what this language means?

:03:11 11 A. Yes.

:03:12 12 Q. Is this one of the three ideas that you discussed  
:03:19 13 during the April 1995 meeting?

:03:22 14 A. Yes.

:03:23 15 Q. Now, let's move to the High-Flex knee project itself.  
:03:39 16 Did there come a time when Zimmer elected to move forward  
:03:44 17 with the development of a High-Flex knee?

:03:47 18 A. Yes.

:03:48 19 Q. Do you know approximately when that was?

:03:53 20 A. It was approximately late '95, '96. In that time  
:04:02 21 frame.

:04:02 22 Q. Who were Zimmer's developer or design surgeons for the  
:04:06 23 High-Flex knee?

:04:08 24 A. The design surgeon team was myself, Dr. Insall, Dr.  
:04:12 25 Scott and even Dr. Kelly.

Scuderi - direct

:04:14 1 Q. To your knowledge, were there any other developer  
:04:18 2 design surgeons?

:04:19 3 A. Not for this project.

:04:21 4 Q. What is it that -- let me ask the question. Do you  
:04:30 5 recognize the term the Gemini Project?

:04:33 6 A. Yes, I do.

:04:34 7 Q. And what was the Gemini Project?

:04:38 8 A. The Gemini Project ultimately became the High-Flex  
:04:43 9 project.

:04:45 10 Q. Would that include High-Flex fixed and high flexed  
:04:52 11 mobile?

:04:52 12 A. Yes.

:04:52 13 Q. Those are devices that you talked about before that  
:04:55 14 are sitting up there. Right?

:04:57 15 A. Yes.

:04:57 16 Q. Now, could you talk about what ISK's design  
:05:04 17 contribution were in the Gemini Project?

:05:09 18 A. So it started with concepts, discussions within the  
:05:16 19 group, myself, Dr. Scott, Dr. Insall, Dr. Kelly, design  
:05:21 20 ideas, conversations, and then with some of the engineers,  
:05:26 21 going on to some prototype concepts, ultimately cadaver  
:05:30 22 surgeries as we discussed earlier, and surgical techniques  
:05:34 23 and procedures, implantations later on.

:05:37 24 Q. You testified just a few minutes ago about design  
:05:42 25 changes to modify the femoral condyles, to improve contact.

Scuderi - direct

:05:48 1 That was one of the contributions to this Gemini Project and  
:05:53 2 the development of those devices?

:05:54 3 A. Yes.

:05:55 4 Q. Were there any other -- let me ask you a question.

:06:00 5 Why was this necessary? What problem was it that you were  
:06:04 6 trying to solve?

:06:06 7 A. As I mentioned earlier, one of the issues was creating  
:06:10 8 the fourth articulation or the posterior superior  
:06:14 9 articulation, so the knee went into flexion well beyond the  
:06:17 10 125. As you approach 155, 160, we would have a smooth  
:06:22 11 articulation, so that we would not have the edge of a  
:06:25 12 component actually digging in and we didn't want to fall off  
:06:28 13 the back.

:06:28 14 THE COURT: So a smooth articulation means more  
:06:32 15 surface.

:06:32 16 THE WITNESS: That is correct. So you want to  
:06:34 17 increase the surface area, as that knee goes into high  
:06:38 18 flexion.

:06:41 19 BY MR. FRIEDMAN:

:06:43 20 Q. Now, did you address the problem with the impinging  
:06:47 21 upon the poly?

:06:49 22 A. So as we went through the iterative process and  
:06:54 23 various design ideas, that modular concept that was  
:06:59 24 originally thought of as one of the options became less of a  
:07:03 25 workable item. And we actually started to just add this

Scuderi - direct

:07:07 1 non-modular component, more material to the back of the  
:07:11 2 femoral component, and create more surface area, as Your  
:07:15 3 Honor had mentioned, to the posterior articulation. So that  
:07:18 4 became the posterior superior articulation.

:07:20 5 We went through various thicknesses, came down  
:07:23 6 from five, three and a half, and down to two millimeters.  
:07:27 7 We were concerned about the amount of bone that we were  
:07:29 8 taking away. But we needed to add that surface area in the  
:07:32 9 back.

:07:33 10 Q. And could you explain to the Court what the sagittal  
:07:38 11 radius means?

:07:39 12 A. The sagittal radius is again from the side view, it's  
:07:42 13 the curve of the component.

:07:47 14 Q. Was there any design input from you at ISK regarding  
:07:53 15 the sagittal radius?

:07:54 16 A. Yes. That was an important part. It was again  
:07:57 17 collaborative with myself, Dr. Scott, Dr. Insall, looking at  
:08:01 18 that radius of the posterior condyles, especially the  
:08:06 19 posterior superior condyle.

:08:06 20 Q. What did the three of you determine would have to be  
:08:09 21 done to solve that problem?

:08:12 22 A. There were design ideas and changes that we presented  
:08:16 23 to the Zimmer engineers in collaboration with them,  
:08:20 24 finalized that radius.

:08:22 25 Q. Now, earlier on in your testimony, you referred to the

Scuderi - direct

:08:28 1 cam-and-spine interaction. I believe you took a model and  
:08:34 2 demonstrated it to the Court. I would like to talk about  
:08:36 3 that for just a minute or two.

:08:40 4 What exactly was the problem that needed to be  
:08:42 5 solved that related to the spine-cam interaction?

:08:47 6 A. So one of the issues with the posterior stabilized  
:08:52 7 knee, it is the interaction of the cam, the bar, to the  
:08:56 8 tibial post. Dr. Rohr alluded to that during his testimony  
:09:00 9 as the original IB design.

:09:05 10 It was riding up. So when he talk about the  
:09:08 11 cam, again, as the cam, showing you from the back, Your  
:09:10 12 Honor, as the cam hits that tibial post, you can see it's  
:09:13 13 riding down, it sits very low, sitting down at the bottom.

:09:17 14 Some other designs, as it rode up, it could  
:09:24 15 actually dislocate and jump the post. So as you go into  
:09:27 16 high flexion you wanted to create a design that provided the  
:09:33 17 necessary movement of the joint, the flexion, the rollback,  
:09:36 18 and the rotation, but you also wanted it to be stable. So  
:09:41 19 you didn't want it to jump.

:09:42 20 So in order to do that we had to modify the cam,  
:09:45 21 that bar.

:09:46 22 The LPS cam was cylindrical. It was rolling  
:09:53 23 down. But the problem was, as you went to high flexion it  
:09:58 24 actually started to move up a little bit. So what we needed  
:10:01 25 to do was create an oblong cam -- and this cam is very

Scuderi - direct

:10:05 1 different than the LPS -- and create a radius, so that as it  
:10:09 2 engaged, it rolled down, stayed down and even in high  
:10:12 3 flexion, you can see, I can't separate it. That provides  
:10:15 4 the stability.

:10:15 5 So those were design ideas and concepts that we  
:10:19 6 collaborated on.

:10:20 7 Q. When you say oblong, it would appear oblong looking at  
:10:24 8 it from the end?

:10:25 9 A. Right. So if I had to do a sagittal cut and cut right  
:10:30 10 through it like a slice of baloney, it was oblong.

:10:33 11 Q. What was the cam-spine -- what was the shape of the  
:10:37 12 cam before that?

:10:38 13 A. So it was cylindrical with the LPS.

:10:43 14 Q. And this was a design contribution made by Dr. Insall,  
:10:48 15 Dr. Scott and yourself?

:10:50 16 A. Yes.

:10:50 17 Q. How was this design contribution communicated to the  
:10:57 18 Zimmer engineers so that they could prepare prototypes?

:11:00 19 A. It was communicated by Dr. Insall to the engineers.

:11:04 20 Q. Could you put up the '729 patent claims again, please?

:11:11 21 Are the concepts that you just described  
:11:21 22 concerning the redesign of the spine-cam mechanism found in  
:11:26 23 the claims of the patent?

:11:28 24 A. Yes, they are.

:11:28 25 Q. Obviously, I have put up 4, 5 and 6. Why don't you

Scuderi - direct

:11:35 1 explain to the Court where the concepts that you came up  
:11:39 2 with for the redesign of the cam-spine mechanism or  
:11:43 3 interaction are found in the claims of the patent?

:11:45 4 A. As you read through 4, 5 and 6, if we go here, the cam  
:11:54 5 having an articulate surface, the cam articular surface  
:11:58 6 contacting the articulate cam surface at varying vertical  
:12:04 7 locations as the femoral and tibial components are flexed  
:12:07 8 relative to one another beyond 90 degrees, the distance from  
:12:11 9 the contact point between the cam and spine articulate  
:12:15 10 surfaces to the spine top surface being greater at 130 than  
:12:20 11 90. That means it's moving downward.

:12:23 12 Q. That is the design you have been talking about?

:12:25 13 A. That's correct.

:12:26 14 Q. Where else?

:12:27 15 A. It goes on, in Claim No. 5, again, it is stating that  
:12:32 16 the Claim 4 within the distance from the contact between the  
:12:36 17 cam and spine articular surface to the top of the spine is  
:12:40 18 approximately the same for angles of 130 to 160 degrees of  
:12:45 19 flexion.

:12:45 20 Again, the importance of that, as I mentioned,  
:12:48 21 is staying low so it's not jumping the spine and  
:12:54 22 dislocating.

:12:55 23 Then finally, on the fourth line at the bottom,  
:12:58 24 it says the cam has a non-cylindrical articular surface,  
:13:04 25 that's the oblong nature of it.



Scuderi - direct

:13:07 1 Q. Thank you.

:13:10 2 Now, during the development of the High-Flex  
:13:17 3 knee products, what were the nature of the intersections  
:13:21 4 generally between you as the developer design surgeons and  
:13:26 5 Zimmer's engineers?

:13:29 6 A. We had numerous interactions. We had multiple  
:13:31 7 meetings. We had cadaver labs and surgical operations.

:13:35 8 Q. When you would have cadaver labs or surgical  
:13:43 9 operations, would they be followed by meetings and  
:13:47 10 brainstorming sessions?

:13:48 11 A. Yes. So usually we would have a meeting before to  
:13:51 12 discuss what the planned cadaver surgery was. We would do  
:13:56 13 the cadaver surgery; have discussions during the cadaver  
:13:59 14 surgery. Then we would have a debrief meeting thereafter,  
:14:03 15 discussing our findings, and what action items needed to be  
:14:07 16 taken.

:14:07 17 Q. How many cadaver studies did you participate in the  
:14:15 18 development of the High-Flex --

:14:18 19 A. There were several. All that were done at the ISK  
:14:20 20 Institute I participated in.

:14:20 21 Q. Was Dr. Scott present during any of them?

:14:24 22 A. Yes.

:14:25 23 Q. The majority?

:14:26 24 A. I would say the majority, if not all. Again, the  
:14:30 25 bioskills lab was right in the same building, right where

Scuderi - direct

:14:33 1 our offices and operating rooms were. So it would be very  
:14:38 2 common for him to come down and be part of it.

:14:41 3 Q. Were there interactions between the surgeons and the  
:14:47 4 Zimmer engineers outside of the meetings or the cadaver  
:14:53 5 studies or the surgeries?

:14:56 6 A. We would meet with the engineers, you know, at times  
:14:59 7 at other meetings, to discuss topics, and they would be in  
:15:02 8 an educational program, the engineers may have been present.  
:15:06 9 There be may have been some discussions at some other  
:15:07 10 venues.

:15:08 11 Q. All right. Could you put up PTX-135, please?

:15:27 12 You see on the screen, as well as in your book,  
:15:31 13 PTX-135. I would like to focus on that, if I could. This  
:15:42 14 is a document that you have seen before?

:15:43 15 A. Yes.

:15:43 16 Q. Now, could you explain to the Court what is being  
:15:52 17 discussed in this document concerning the design solutions  
:15:58 18 we have been talking about?

:16:01 19 A. So in this particular letter from Mark Heldreth to  
:16:07 20 John Insall, if we go to the second paragraph, regarding the  
:16:15 21 design, Please find enclosed two decentralized layouts of  
:16:20 22 the Size D high-flexion knee. It goes on to discuss the  
:16:28 23 posterior radius, which you saw in the original prototype.  
:16:29 24 It describes changes in the radius, and the statement that  
:16:36 25 the posterior condyles have been reduced two millimeters in

Scuderi - direct

:16:38 1 height from the original LPS, as done in the original  
:16:41 2 mockup.

:16:42 3 Then it goes on to, you know, ask the question.

:16:45 4 Q. Before we get to that, what you just talked about  
:16:48 5 relates to the design of the sagittal radius that the  
:16:55 6 surgeons had talked about before, that was communicated to  
:17:00 7 Zimmer?

:17:01 8 A. That is correct.

:17:02 9 Q. Now, let's go to the question or questions that you  
:17:09 10 were alluding to in the next paragraph?

:17:10 11 A. The question from the engineers is how far anterior do  
:17:14 12 we want the femoral, the femur, it's a typo, to be in deep  
:17:20 13 flexion. It would appear that the distance, the balance  
:17:23 14 between the desire to avoid having the femoral, again he has  
:17:28 15 a typo, the femur coming off the back and avoiding femoral  
:17:32 16 bone, tibial bone impingement. So, again, a problem. And  
:17:36 17 the question was, two millimeters.

:17:38 18 Q. Is this an example of where Zimmer is looking to the  
:17:46 19 surgeons to develop a design to solve a problem?

:17:49 20 A. Yes. This is the Zimmer engineers presenting to us a  
:17:53 21 problem and requesting from us a solution.

:17:58 22 Q. Let's just take a look at the next paragraph briefly,  
:18:05 23 and explain to the Court what this is?

:18:08 24 A. So, in that final paragraph on the page, the  
:18:12 25 additional two-millimeter movement of the cam allows the

Scuderi - direct

1 femur to move even farther away from the posterior edge of  
2 the articular surface. It results, however, in the  
3 spine-cam jump height safety factor being reduced.

4 So in this particular question or statement, it  
5 again relates to changes or modifications to the spine-cam  
6 mechanism. The engineers were removing some material. By  
7 removing it off the cam it actually translocates the femur  
8 in a more anterior position.

9 So what would happen is, if you took some  
10 material off, that effectively, I am going to hold it this  
11 way, move the tibia a little bit more, so it moves it  
12 forward, changes the position. But by doing that it affects  
13 the movement of the joints, very subtly.

14 What happens is, we don't have the benefit of  
15 bones here, but by doing that, think of a bone here and a  
16 bone here, that meant you get bony impingement that would  
17 block movement. So think of it as a mechanical stop,  
18 because by moving that component more interiorly, flexing  
19 the knee, the two bones would collide. That would cause  
20 impingement. That would cause pain or even restriction of  
21 movement.

22 So again, very subtle change, two millimeters,  
23 was really affecting how that knee was going to ultimately  
24 bend. That was a question that was being posed to us at  
25 that point in time.

Scuderi - direct

:19:33 1 Q. And why was it being posed to you?

:19:36 2 A. Because we were the design team.

:19:40 3 MR. HALES: Your Honor, same foundation  
:19:43 4 objection.

:19:43 5 THE COURT: I am sorry.

:19:45 6 MR. HALES: The question was why was this being  
:19:47 7 posed to them. The letter is authored by somebody other  
:19:52 8 than Dr. Scuderi.

:19:55 9 THE COURT: You understand his objection.

:19:57 10 BY MR. FRIEDMAN:

:19:57 11 Q. I do. Did you have an understanding of why Zimmer was  
:20:00 12 coming to ISK with this question?

:20:02 13 A. Yes.

:20:03 14 Q. Strike that. What was your understanding of the  
:20:07 15 purpose for the question being asked?

:20:10 16 A. The reason being --

:20:11 17 THE COURT: Do you object to that question, his  
:20:13 18 understanding of the reason?

:20:16 19 MR. HALES: In this case if he can establish  
:20:17 20 that he has a basis for a reason, then the next question  
:20:20 21 might be appropriate. I think he is essentially trying to  
:20:22 22 elicit the same answer.

:20:23 23 THE COURT: Restate the question.

:20:25 24 (Pending question read.)

:20:36 25 THE COURT: Wouldn't the answer be he is part of

Scuderi - direct

:20:39 1 the design team?

:20:45 2 MR. HALES: Yes.

:20:46 3 THE WITNESS: So if we go to the last line of  
:20:48 4 the letter, the last line of the letter on Page 2, they were  
:21:02 5 coming in for a cadaver study on September 19th. So, again,  
:21:07 6 Dr. Insall shared this letter with us in preparation for our  
:21:10 7 cadaver lab, which was going to be a week or two later.

:21:15 8 BY MR. FRIEDMAN:

:21:16 9 Q. Let's go to 137, PTX-137. Just enlarge it a little  
:21:25 10 bit.

:21:25 11 Now, do you recognize PTX-137?

:21:34 12 A. Yes, I do.

:21:34 13 Q. You have seen that before?

:21:36 14 A. Yes, I have.

:21:37 15 Q. And it refers to a cadaver evaluation that, in fact,  
:21:42 16 took place following the exhibit we just looked at at ISK.  
:21:46 17 Correct?

:21:47 18 A. Yes.

:21:47 19 Q. Briefly, what does this letter show as having occurred  
:21:55 20 at the cadaver study?

:21:59 21 A. Again, this letter summarizes the cadaver study, and  
:22:06 22 it reported our observations during the cadaver evaluation  
:22:10 23 with the implant that was mentioned in the prior letter.

:22:15 24 Q. How do these two documents that we just looked at,  
:22:19 25 PTX-135 and PTX-137, exemplify the design interactions

Scuderi - direct

:22:26 1 taking place between the design surgeons at ISK and Zimmer  
:22:30 2 engineers?

:22:31 3 A. So this shows us that the interaction included  
:22:38 4 correspondence with prototype ideas, features that we have,  
:22:44 5 design ideas that we shared with Zimmer, Zimmer creating  
:22:48 6 prototypes, looking at those specific prototypes, posing  
:22:52 7 questions to us, problems that they may observe.

:22:56 8 This thing goes on to the cadaver lab, where we  
:23:00 9 make similar observations. And then give further action  
:23:04 10 items for the next steps.

:23:06 11 Q. And are the designs with respect to cam-spine that are  
:23:13 12 reflected in these documents relating to the cadaver study  
:23:17 13 found in the '729 patent?

:23:22 14 A. Yes.

:23:22 15 Q. Could you put up Claim 6, please. How are the design  
:23:34 16 subjects that were discussed in these two documents  
:23:36 17 surrounding the cadaver study reflected in the patent?

:23:39 18 A. Again, this relates to the interaction of the  
:23:42 19 spine-cam mechanism, trying to keep that jump height low.  
:23:46 20 It actually includes from four to six. Again, as I  
:23:49 21 mentioned earlier and showed you on the modeling, we want to  
:23:52 22 keep that jump height, you know, low.

:23:55 23 And again, as we had gone through different  
:24:01 24 design changes, looking at the appropriate thickness of the  
:24:03 25 spine-cam to provide the stability that we need, as well as

Scuderi - direct

:24:06 1 the impact of the spine-cam mechanism on high flexion.

:24:10 2 Q. Now, during this case, many, many documents have been  
:24:19 3 shown to you. Correct?

:24:20 4 A. Yes.

:24:22 5 Q. Do you remember all of them?

:24:24 6 A. Not all of them.

:24:25 7 Q. During your deposition, you were asked about some  
:24:29 8 documents and where they came from. Do you remember that?

:24:32 9 A. Yes.

:24:32 10 Q. And during your deposition, you indicated that there  
:24:40 11 were some documents that you hadn't seen that may have come  
:24:43 12 from Dr. Scott's files. Correct?

:24:45 13 A. That's correct.

:24:45 14 Q. After the deposition, did you do anything to determine  
:24:50 15 where the documents that you had not seen actually came  
:24:54 16 from?

:24:54 17 A. Yes, I did.

:24:55 18 Q. And what were you able to determine?

:24:58 19 A. Well, I looked into where documents had arisen from,  
:25:05 20 and went back to talk to my secretarial staff as to the  
:25:10 21 reason some of this material had come to my attention.

:25:15 22 It became apparent to me that when Dr. Insall  
:25:18 23 passed away in 2000, December of 2000, actually, his wife  
:25:24 24 had come by and picked up his personal effects, personal  
:25:28 25 items in the office, as well as some files and records. The



Scuderi - direct

1 rest was placed in boxes within a closet.

2 In 2004, the ISK Institute was relocated to  
3 another facility. Because the new facility and the office  
4 space really did not have adequate storage, those boxes were  
5 sent to a storage facility. Those boxes were there for  
6 about two years. In those boxes were numerous books and  
7 other material from the libraries and research packets,  
8 boxes were sealed and labeled.

9 In 2006, we relocated the office.

10 MR. HALES: Your Honor, I am wondering if we can  
11 have a brief sidebar. I apologize to interrupt the  
12 question. But there is something I think we should have a  
13 discussion about.

14 (The following took place at sidebar.)

15 MR. HALES: Your Honor, none of this information  
16 has ever been disclosed in his report. We have had  
17 extensive efforts, as the Court is aware, trying to figure  
18 out what happened to Dr. Insall's records. We subpoenaed  
19 ISK. We had a deposition of ISK. We subpoenaed Dr.  
20 Insall's widow, you know the stipulation that we got from  
21 her. Both Dr. Scott and Scuderi were asked about the  
22 location of those documents repeatedly. And at no point has  
23 there been any supplementation of the prior answers or any  
24 information provided about these apparent subsequent  
25 investigations that Dr. Scuderi is now revealing for the

Scuderi - direct

:39:09 1 first time at trial.

:39:09 2 MR. FRIEDMAN: Actually, at his deposition and  
:39:09 3 here, he will be asked whether this is a document you have  
:39:09 4 seen before, where the document came from and so forth.  
:39:09 5 That arose for the first time at the deposition.

:39:09 6 Frankly, it was only within the last 24 hours  
:39:09 7 that he was able to figure out how he ended up with sealed  
:39:09 8 boxes in his -- I don't remember what he said, his garage or  
:39:09 9 his basement, because there was no other place to put them,  
:39:09 10 they sat there until we were served with a document  
:39:09 11 production request.

:39:09 12 And we asked Dr. Scuderi to gather up everything  
:39:09 13 that he has, wherever it may be located, and to produce it  
:39:09 14 for them.

:39:09 15 THE COURT: When was the document production  
:39:09 16 request?

:39:09 17 MR. FRIEDMAN: Let's say a year ago.

:39:09 18 THE COURT: Some time ago. That is sort of a  
:39:10 19 rhetorical question, I guess.

:39:10 20 MR. FRIEDMAN: Sure.

:39:10 21 THE COURT: Counsel?

:39:10 22 MR. HALES: My point is, what I am talking about  
:39:10 23 is not the documents that were produced to us. They were  
:39:10 24 produced to us by Dr. Scott or Dr. Scuderi. What I am  
:39:10 25 saying is, they have been -- this notion of this very -- I

Scuderi - direct

:39:10 1 don't know when this investigation happened. At the  
:39:10 2 depositions in this case, nobody could testify as to -- they  
:39:10 3 denied knowing where these documents came from, even though  
:39:10 4 clearly they were produced by one of the two doctors. They  
:39:10 5 are market with the S&S stamp. We asked about that. They  
:39:10 6 said, they didn't give this. We have tried to figure out if  
:39:10 7 they were ISK. We tried to figure out if they were with  
:39:10 8 Mrs. Insall. What Dr. Scuderi is now saying is he has done  
:39:10 9 some further investigation, trying to track down where these  
:39:10 10 documents came from and why he had them. That's never been  
:39:10 11 revealed to us.

:39:10 12 It is apparently an investigation that they did,  
:39:10 13 I think Mr. Friedman might have said within the last 24  
:39:10 14 hours, to figure this out.

:39:10 15 This has been an issue that they know we have  
:39:10 16 been chasing for six months.

:39:10 17 THE COURT: Let me ask you this before you  
:39:10 18 respond. The documents that are at issue right now, they  
:39:10 19 have been produced. Right?

:39:10 20 MR. HALES: Yes.

:39:10 21 THE COURT: These documents were found sealed at  
:39:10 22 Dr. Scuderi's house.

:39:10 23 MR. FRIEDMAN: They were in boxes at his house.

:39:10 24 THE COURT: But you have the documents.

:39:10 25 MR. HALES: I have the documents, yes.

Scuderi - direct

1 THE COURT: So this apparent revelation that  
2 occurred to the doctor, which led to this investigation,  
3 occurred, this revelation occurred within the last 24 hours.

4 MR. FRIEDMAN: Right. But it may be helpful if  
5 I explain why I am even asking the question, because then  
6 Your Honor can determine if it is relevant or not.

7 At his deposition, he was shown a particular  
8 document, which they are going to bring up in their case.  
9 It has an S&S Bates stamp number, which means it came from  
10 the Scott and Scuderi document collection.

11 He was asked at his deposition, do you know  
12 where this particular document came from, the document  
13 relating to patents and stuff.

14 My recollection is he said, it may have come --  
15 it didn't come from my file. I have never seen it. It may  
16 have come from Dr. Scott's files.

17 Well, it turns out that that document did not  
18 come from Dr. Scott's files, but was in this -- I think  
19 there were five boxes of documents that he had in his  
20 basement, all of which were produced to Zimmer with S&S  
21 Bates stamp numbers. And I just want to put this in to  
22 explain that the document that he is going to want to rely  
23 upon did not come from Dr. Scott's files, just because it  
24 has an S&S Bates stamp number, and that our client probably  
25 was mistaken when he said it might have come from Dr.

Scuderi - direct

1 Scott's file.

2 That is the context for this.

3 THE COURT: So, obviously, what we are trying to  
4 avoid, trial by surprise. You aren't surprised by this.

5 MR. HALES: What I am surprised by is the new  
6 revelation that changes the dynamic of where these documents  
7 originate from. It is something they have never been able  
8 to explain before. Why is this investigation happening in  
9 the last 24 hours to try to modify their case on the origin  
10 of these documents? That is my concern.

11 THE COURT: Does that result in a modification  
12 of the case?

13 MR. HALES: Yes. Before it was that document  
14 probably came from Dr. Scott's files. Now it is that  
15 document didn't come from Dr. Scott's files.

16 THE COURT: Given I don't hear prejudice at this  
17 point, you have got the documents, you have got the witness,  
18 you can certainly cross-examine him. I think he is  
19 preemptively trying to ask some questions in anticipation of  
20 that cross-examination. I don't know it's going to have --  
21 this is going to have a big impact on the fact-finder in  
22 terms -- are you concerned about credibility or perhaps some  
23 concern that there was some effort to hide the ball?

24 MR. HALES: The issue goes directly to the scope  
25 of Dr. Scott's release. As you know from the presentation

Scuderi - direct

1 yesterday or at least as I have conveyed, Doctor Scott's  
2 release is on a "knew or could we have known standard" and  
3 we have gone through this case up until this very moment  
4 with the belief that this document, according to Dr.  
5 Scuderi, must have come from Dr. Scott's files. Now we are  
6 learning, during the trial, that that story has changed. So  
7 that does have an effect on us.

8 THE COURT: What is key?

9 MR. FRIEDMAN: Remember, I represent both Dr.  
10 Scott and Dr. Scuderi, even though this other fellow is  
11 taking the lead on that part of the case.

12 I am trying to deal with this issue of whether  
13 this document which Mr. Hales is going to want to rely upon  
14 actually came from Dr. Scott's files, in which case they are  
15 going to charge him with notice of something.

16 MR. HALES: Yes.

17 MR. FRIEDMAN: That is the context.

18 THE COURT: I will hear it, subject to a  
19 continued objection, perhaps a motion to strike. Let me  
20 listen.

21 MR. FRIEDMAN: I am almost finished.

22 THE COURT: I know it will not take a lot of  
23 time. I don't think that's counsel's concern. Let's  
24 listen.

25 MR. HALES: Your Honor, subject to a possible

Scuderi - direct

:39:10 1 motion to strike, is that something you want me to assert?

:39:10 2 THE COURT: It is preserved. But you should  
:39:10 3 assert it.

:39:10 4 MR. HALES: Immediately today or at the  
:39:10 5 post-hearing brief?

:39:10 6 THE COURT: You may want to think about it. If  
:39:10 7 you want to renew it, you can. I am not sure I would be  
:39:10 8 inclined to grant it today. But I am not going to take it  
:39:10 9 off the table altogether. It may be that at some  
:39:10 10 appropriate time when you have even better context that it  
:39:10 11 may be proper for me to reconsider this ruling.

:39:10 12 Could I go off the record.

:39:10 13 (Discussion off the record.)

:39:13 14 THE COURT: Counsel, we are going to break at  
:39:16 15 noon today for lunch for about an hour.

16 MR. FRIEDMAN: Can you read where we were?

:39:19 17 (Record red as requested.)

:40:41 18 Q. Can you pick up where you left off?

:40:44 19 A. In 2006, we relocated the office to our current  
:40:47 20 facility. We reestablished the library and the conference  
:40:51 21 room, books and materials were sent up. Dr. Insall and I  
:40:55 22 shared a common secretarial staff. There were some boxes  
:41:00 23 that had documents in it. The secretaries put those boxes  
:41:03 24 in my room. They were sealed. Once I saw the boxes, I just  
:41:07 25 slipped them under my desk. I had no need to open them or

Scuderi - direct

:41:11 1 look at them in 2006.

:41:13 2 Over time, my office got a little bit crowded  
:41:18 3 and it's tough storing boxes under your desk. I took those  
:41:22 4 boxes, again, sealed boxes, sent them to my home, stored in  
:41:25 5 my basement. A couple went to the garage. That's where  
:41:28 6 they stayed until 2009, when I started to look into the  
:41:33 7 documents.

:41:33 8 Q. Could we have PTX-137, please, if you would look at  
:41:42 9 that, I would appreciate it.

:41:50 10 A. Okay.

:41:50 11 Q. Now, going again to Page 2 of this exhibit, if I  
:42:08 12 might, on Page 2, there are a number of design features that  
:42:13 13 are discussed. Correct?

:42:14 14 A. Yes.

:42:14 15 Q. And at Page 1, it indicates Drs. Insall, Kelly,  
:42:25 16 Scuderi and Stern were in attendance. Correct?

:42:29 17 A. Yes.

:42:29 18 Q. Do you know, by the way, whether Dr. Scott was also in  
:42:34 19 attendance, even though his name is not mentioned?

:42:37 20 A. Yes, he would have been there.

:42:39 21 Q. So these meeting results that are described on Page 2  
:42:45 22 were contributed to by whom?

:42:49 23 A. By the design team surgeons, Dr. Insall, myself, Dr.  
:42:54 24 Kelly, and Dr. Scott.

:42:56 25 Q. And are these the same features that you identified as



Scuderi - direct

:43:01 1 being in Claims 4 through 6 of the '729 patent?

:43:07 2 A. This is actually -- it's 4 and 6, as well as No. 1.

:43:14 3 Q. Now, can we go to PTX-152. PTX-152 is a document that  
:43:32 4 was sent to you by Mark Heldreth. Correct?

:43:35 5 A. Yes.

:43:36 6 Q. And if you could -- are these notes also from a  
:43:41 7 cadaver study?

:43:51 8 A. These notes are in preparation for upcoming  
:43:58 9 surgical --

:43:58 10 Q. One of those live surgeries that you talked about?

:44:02 11 A. Yes.

:44:03 12 Q. Could you explain to the Court what the second  
:44:11 13 paragraph -- and let's focus on that -- what it means and  
:44:17 14 what your understanding is, as to why it is there?

:44:21 15 MR. HALES: Foundational objection, Your Honor.

:44:24 16 THE COURT: Could you ask a foundational  
:44:26 17 question.

:44:27 18 BY MR. FRIEDMAN:

:44:27 19 Q. This is a document that was sent to John Insall,  
:44:30 20 copied to you. Correct?

:44:31 21 A. Yes.

:44:31 22 Q. What was your understanding of why Mr. Heldreth was  
:44:39 23 presenting you with the information that he was concerning  
:44:43 24 new posterior cutting and so forth?

:44:47 25 A. So, again, as part of the design team, Mark Heldreth

Scuderi - direct

:44:53 1 included me in this letter to John Insall announcing that he  
:44:58 2 was coming. We had planned surgery, and even a cadaver  
:45:01 3 study thereafter. We were looking at dead prototypes that  
:45:05 4 he was bringing.

:45:06 5 Q. And again, this exemplifies the kind of design  
:45:09 6 give-and-take that ISK had with the engineers?

:45:13 7 A. Yes, that's correct.

:45:15 8 Q. If we could take a look at PTX-189. PTX-189 was  
:45:38 9 received by you. Correct?

:45:40 10 A. Yes.

:45:40 11 Q. What does PTX-189 -- and I am referring particularly  
:45:48 12 to the minutes -- represent?

:45:50 13 A. It's minutes of a cadaver meeting at the ISK Institute  
:45:54 14 June 25th to 26th, 1998.

:45:57 15 Q. All right. By the way, do you recall whether Dr.  
:46:02 16 Scott also attended this?

:46:04 17 A. Dr. Scott was there, also.

:46:06 18 Q. Even though he is not listed on the distribution list  
:46:10 19 or as attending?

:46:12 20 A. Again, he is not listed.

:46:14 21 Q. And what does -- if we can focus on the second  
:46:18 22 paragraph of this, what does this represent?

:46:25 23 A. Again, this relates to the jump height, which is the  
:46:28 24 spine-cam mechanism. Again, the articulation of the femur  
:46:35 25 on the tibia, it talks about jump height, that is the

Scuderi - direct

:46:39 1 position of the cam, femoral cam on the tibial spine.

:46:43 2 Q. And this is one of the design features that was found  
:46:46 3 in the '729 patent?

:46:48 4 A. Yes, four to six.

:46:52 5 Q. Four to six, okay.

:46:53 6 Let's change subjects briefly and go to  
:47:00 7 something which is called liftoff.

:47:02 8 Could you explain to the Court what the liftoff  
:47:07 9 problem was? And if you want to use the devices, just go  
:47:12 10 ahead.

:47:13 11 A. So during our testing, the engineers have to put all  
:47:18 12 implants through a vigorous testing to see how durable they  
:47:22 13 would be in the patient. These are usually adverse  
:47:24 14 conditions, may or may not be seen in the human body. But  
:47:28 15 we are required for a multitude of reasons, including the  
:47:31 16 FDA, to test these products.

:47:33 17 One of the testings was looking at the locking  
:47:36 18 mechanism of the fixed bearing, as well as the stability of  
:47:42 19 the mobile bearing.

:47:46 20 What the engineers did was, they put the plastic  
:47:50 21 onto the tray, snapped it in place, they put the femoral  
:47:54 22 component in a high degree of flexion, putting all the load  
:47:57 23 on the back condyle. And they applied an exceptionally high  
:48:01 24 load.

:48:02 25 What they observed when the femoral component

Scuderi - direct

:48:04 1 started pressing down on the back of the knee is that the  
:48:09 2 polyethylene would start to creep out. It would start to  
:48:12 3 lift out -- sorry, the string is holding me down -- but  
:48:16 4 start to creep up. This would create a dissociation, a  
:48:20 5 separation of the parts, possibly, you know, in the human  
:48:23 6 body, that would be catastrophic failure.

:48:25 7 So that was the one testing. That posed a  
:48:29 8 problem. We had to figure out how to resolve that. We  
:48:33 9 needed, you will see in the terminology, a robust locking  
:48:36 10 mechanism. We had to come up with a solution. That was a  
:48:39 11 problem we identified with the fixed.

:48:40 12 In a similar fashion with the mobile -- this one  
:48:44 13 I am not going to be able to do because it is locking pretty  
:48:48 14 tight -- but again, as you applied the load in the back,  
:48:51 15 similar to what I just showed you on the fixed -- if I can  
:48:55 16 pull this out for you -- it doesn't fit, it's the string, I  
:49:00 17 figured, that's holding me down -- but if you applied the  
:49:03 18 load in the back, again, I am going to leave it in an  
:49:06 19 exaggerated position, you can see that I could jump over the  
:49:09 20 trunnion, again, a problem. Very adverse condition, but  
:49:13 21 that was problematic and we had to solve that problem.

:49:16 22 That's the liftoff, anterior liftoff that they  
:49:20 23 were talking about.

:49:21 24 Q. The anterior liftoff problem existed in both the fixed  
:49:24 25 and the mobile?

Scuderi - direct

:49:25 1 A. That's correct.

:49:26 2 Q. Now, could you put up PTX-191, please. If you look at  
:49:32 3 it in your book, Dr. Scuderi, please. We probably can't get  
:49:39 4 all of it on the screen in a way that anybody could really  
:49:43 5 read it. I know how you doctors write.

:49:49 6 Could you explain to the Court first what this  
:49:52 7 document is and why it was prepared?

:49:57 8 A. This is my handwriting, and when the problem was posed  
:50:03 9 to us, I started to think about a possible solution. And  
:50:11 10 this particular document is my ideas on a solution for the  
:50:18 11 liftoff. It states, High-Flex fixed-bearing tibial tray,  
:50:24 12 design ideas.

:50:24 13 Q. And at the bottom is a signature, is that your  
:50:27 14 signature?

:50:27 15 A. Yes, that's my signature and a date.

:50:31 16 Q. What is the date, 8/4/98?

:50:34 17 A. That's correct, August 4, 1998.

:50:36 18 Q. Why did you sign this document?

:50:38 19 A. I don't recall any reason why I signed that document.

:50:43 20 Q. Did Dr. Insall and Dr. Scott have any design input for  
:50:50 21 the creation of the designs that you are describing in this  
:50:52 22 document?

:50:52 23 A. So once -- there are some drawings that come up after  
:50:56 24 this particular document, too. It's a three-page document.  
:51:00 25 But I shared that information with Dr. Insall and Dr. Scott

Scuderi - direct

:51:03 1 and again very much trying to collaborate -- this was a  
:51:06 2 problem that was posed to us by the engineers. Can we solve  
:51:08 3 it? And this is where I, you know, came up with at least  
:51:12 4 this idea that we were entertaining.

:51:16 5 Q. Could you go, I guess, to the part of the document  
:51:22 6 marked 1178 at the bottom, and just explain to the Court  
:51:28 7 briefly what that represents?

:51:31 8 A. So you can see the drawing in the upper left-hand  
:51:35 9 corner is a tibial tray. The polyethylene component it  
:51:40 10 shows you, it is a screw, it is a locking mechanism. You  
:51:45 11 put a hole through the tibial polyethylene, pass it through  
:51:48 12 the hollow of the tibial stem, and then put a washer, or a  
:51:56 13 plug which the screw can engage and lock it in place.

:52:00 14 As you can see, the problem and the solution was  
:52:02 15 one to create a more robust locking mechanism and to lock  
:52:06 16 that poly into place. The pictures go on to talk about  
:52:13 17 using a torque wrench because you want to make sure, if you  
:52:17 18 put a screw in, it really locks it in. It is not going to  
:52:21 19 back out in time as things move. We talked about on the  
:52:25 20 bottom, in the right, this is more tapered. I was looking  
:52:28 21 at a taper plug type of fixation.

:52:30 22 Q. Is this design adaptable to the mobile-bearing knee?

:52:34 23 A. Well, you know, again, you know, at the same time we  
:52:37 24 were looking at a design to lock that down.

:52:40 25 The benefit -- the one problem with the tibial

Scuderi - direct

:52:43 1 trays is that as you can see it's hollow and we had no way  
:52:47 2 of locking it down. It didn't have threads within it. That  
:52:50 3 is why we had to put a washer and taper plug at the bottom.  
:52:54 4 That is why we added the extra piece and the screw. We used  
:52:56 5 that for the thicker polyethylene components.

:52:58 6 The mobile, we had the benefit of having the  
:53:04 7 projection off the tray. In a similar fashion, we can lock  
:53:09 8 that in place. And actually, I have the screw right here.  
:53:11 9 So we took a screw, and put it right into the trunnion, and  
:53:15 10 that was, again, to thread and lock that into place so it  
:53:20 11 wouldn't lifted off.

:53:21 12 So we were locking it in. It still can rotate,  
:53:25 13 but as you applied the loads, because it can lock down, it  
:53:29 14 wouldn't lift down.

:53:29 15 Q. If these design concepts were usable for both the  
:53:33 16 fixed-bearing and the mobile bearing, why was this document  
:53:36 17 titled High-Flex?

:53:37 18 A. Well, it's a document on High-Flex because it was a  
:53:40 19 High-Flex concept and the fixed-bearing aspect of it was  
:53:43 20 because that was the more problematic one because we had to  
:53:46 21 figure out, how do we create a more robust locking  
:53:50 22 mechanism. How do we lock that one done down? We were  
:53:54 23 talking about both simultaneously.

:53:55 24 Q. Could you put up the '283 patent, please.  
:54:02 25 Particularly, the claims.

Scuderi - direct

:54:06 1 What exhibit is this, please?

:54:16 2 PTX-3.

:54:18 3 Are the design concepts that were reflected in  
:54:33 4 your handwritten memorandum, which is identified as PTX-191,  
:54:42 5 found in the claims of the '283 patent?

:54:46 6 A. Yes. Nos. 1 to -- 9 to 12.

:54:51 7 Q. Could you enlarge 9 to 12, please?

:54:54 8 Just explain to us where and how the designs  
:55:02 9 that you just talked about that you conceived of with input  
:55:05 10 from Dr. Insall and Dr. Scott are found in Claims 9 through  
:55:11 11 12?

:55:12 12 A. As I said, we were collaborating on a locking  
:55:14 13 mechanism for the mobile-bearing at the same time as we were  
:55:19 14 working on the fixed-bearing tibial component. As I  
:55:23 15 mentioned earlier, in this particular case we knew we had to  
:55:26 16 get the screw through the polyethylene, especially for the  
:55:29 17 thicker ones. As we see here in No. 9, it states that a  
:55:33 18 tibial tray including a proximal tibial plateau extending --  
:55:39 19 a projection generally extending orthogonal from the said  
:55:44 20 tibial plateau and defining an axis of rotation, that is the  
:55:48 21 trunnion, extending upward. A bearing carried by said  
:55:52 22 tibial tray and having an opening in which said projection  
:55:56 23 is disposed, that is again the hole in the tibial tray. It  
:55:59 24 goes on, allowing rotational movement, it says a fastener  
:56:06 25 extending through said opening and attached to said



Scuderi - direct

:56:08 1 projection, said fastener seating against said shoulder,  
:56:13 2 said fastener inhibiting movement of said bearing relative  
:56:16 3 to tibial plateau in a direction parallel to the axis of  
:56:20 4 rotation.

:56:21 5 Q. Is the fastener the screw?

:56:22 6 A. The screw, that is correct.

:56:24 7 Q. And is this reflected, also, in Claims 10 through 12?

:56:28 8 A. Yes, it is.

:56:28 9 Q. Now, this drawing is dated August 4, 1998. Was this  
:56:38 10 design finished and complete at that point?

:56:42 11 A. No, it was not.

:56:43 12 Q. What happened after that with respect to the design?

:56:48 13 A. So, again, you know, through collaboration with Dr.  
:56:52 14 Insall, Dr. Scott, even Dr. Kelly, we went on and worked  
:56:57 15 further on the locking mechanism.

:56:59 16 Q. All right. I would like to look at Exhibit PTX-203,  
:57:06 17 please. What does this refer to?

:57:26 18 A. This particular document refers to a cadaver lab that  
:57:30 19 we had at the ISK Institute on December 16th-17th, 1998.

:57:37 20 Q. And this document reports the observations that were  
:57:40 21 made by the design team at the cadaver study?

:57:45 22 A. That is correct.

:57:45 23 Q. And also it contains meeting minutes. Correct?

:57:50 24 A. That is correct.

:57:50 25 Q. And finally, the design team is given followup design

Scuderi - direct

:57:57 1 details. Those appear on the next page?

:58:00 2 A. That is correct.

:58:00 3 Q. Of the exhibit?

:58:01 4 Now, what does this show about the design work  
:58:06 5 that was continuing by you and the other members of the  
:58:10 6 design team on the screw-down?

:58:14 7 A. Again, at this meeting, we looked at various features  
:58:19 8 of the mobile prosthesis. One was the screw-down mechanism.  
:58:28 9 It also looks at the degree of rotation on the articulation.  
:58:36 10 And it looks at the shape and size of the trunnion.

:58:40 11 Q. All right. Could you put up the '283 patent and  
:58:45 12 particularly the columns with Claims 3 and 4, please?

:58:51 13 Are the design features that you just described  
:59:03 14 that are summarized in PTX-203 that were arrived at during  
:59:13 15 the cadaver study and in the post-cadaver meeting reflected  
:59:19 16 in the claims of the '283 patent?

:59:23 17 A. Yes, they are.

:59:23 18 Q. And where are they specifically reflected?

:59:29 19 A. In Claim No. 3, where it says rotationally movable  
:59:34 20 through an angle of approximately 50 degrees. That's here  
:59:40 21 where we stated that we wanted the rotation to be plus or  
:59:44 22 minus 25 degrees, in contrast to plus or minus 30 degrees.  
:59:49 23 So at that point we elected the 50-degree arc of rotation.

:59:55 24 Q. And are these design features that are described in  
:00:01 25 PTX-203, Heldreth's summary memorandum, also found in Claim

Scuderi - direct

:00:09 1 4?

:00:10 2 A. Yes, they are.

:00:11 3 Q. And that's where?

:00:13 4 A. That's the tibial tray including a proximal tibial  
:00:17 5 plateau, a projection extending generally orthogonal from  
:00:21 6 said tibial plateau and defining an axis of rotation.

:00:26 7 That's where we discussed the trunnion and the  
:00:30 8 trunnion height.

:00:30 9 Q. And the lock-down mechanism that is described in here,  
:00:33 10 I think you testified, is also found in Claims 9 through 12.  
:00:37 11 Correct?

:00:37 12 A. Yes.

:00:37 13 Q. All right.

:00:39 14 THE COURT: Why don't we take our lunch.

:00:46 15 MR. FRIEDMAN: I have a one-minute document,  
:00:48 16 then a totally different subject area.

:00:51 17 BY MR. FRIEDMAN:

:00:51 18 Q. Could we go to PTX-176, please. To the next page.  
:01:10 19 You have seen this document before?

:01:12 20 A. Yes, I have.

:01:13 21 Q. Now, this was sent to you by Lazzeri on April 22,  
:01:20 22 1999. Correct? That is shown in the first page that I  
:01:23 23 skipped.

:01:27 24 A. Yes.

:01:27 25 Q. What does this document represent?

Scuderi - direct

:01:29 1 A. This is the updated system overview for the Gemini  
:01:34 2 Project to include the LPS Flex fixed-bearing and  
:01:40 3 mobile-bearing knee system.

:01:42 4 Q. Can you go to the next page, please. Up at the top,  
:01:51 5 the paragraph that begins the LPS Flex Femoral, what does  
:01:56 6 that say about the ISK doctors?

:01:59 7 A. The LPS Flex Femoral, which can be used with fixed or  
:02:02 8 modular bearing tibial trays, provides us with a product  
:02:04 9 that is unmatched by the competition. Our engineers and  
:02:09 10 developing surgeons, Dr. Insall Gil Scuderi, Mike Kelly and  
:02:14 11 others have designed this product to give every patient the  
:02:17 12 opportunity to safely achieve their maximum R.O.M., which is  
:02:22 13 range of motion.

:02:22 14 Q. Okay. And in the balance of the document -- I  
:02:26 15 promised one minute and I am not going to take more than  
:02:28 16 that -- it describes the many different design features that  
:02:33 17 were contributed to, made by that design team. Correct?

:02:38 18 A. Yes.

:02:38 19 MR. FRIEDMAN: This is a good time, Your Honor.

:02:40 20 THE COURT: Let's come back at 1.

:02:42 21 (Luncheon recess taken.)

:08:28 22 THE COURT: Good afternoon, counsel. Please,  
:03:49 23 take your seats.

:03:51 24 MR. FRIEDMAN: Good afternoon, Your Honor.

:03:53 25 THE COURT: Let's resume.

Scuderi - direct

:03:54 1 BY MR. FRIEDMAN:

:03:59 2 Q. Dr. Scuderi, as I mentioned right before the lunch

:04:02 3 break, we are going to move into a different subject area.

:04:06 4 I am going to ask you about a couple of agreements that you

:04:13 5 had with Zimmer.

:04:16 6 Let me start by asking, in fact, you did have

:04:19 7 some royalty agreements with Zimmer. Correct?

:04:25 8 A. Yes.

:04:25 9 Q. And did you have a royalty agreement that pertained to

:04:31 10 the development of the High-Flex?

:04:33 11 A. Yes.

:04:34 12 Q. Could you just describe briefly what it was? Then we

:04:39 13 will put it up on the screen.

:04:40 14 A. It was a license and development agreement for a

:04:43 15 High-Flex implant, both fixed and mobile-bearing.

:04:47 16 Q. Could you put up on the screen PTX-38?

:04:52 17 Turn to the page marked 23402. If you could

:05:00 18 find it in your book, that would be helpful.

:05:04 19 Is the licensing consulting agreement which is

:05:14 20 found at Bates stamp 23402 in this exhibit the license and

:05:22 21 consulting agreement for the High-Flex that you just

:05:25 22 referred to?

:05:26 23 A. Yes.

:05:26 24 Q. And, now, if you turn to -- bear with me -- the page

:05:38 25 that's marked 23429, that's your signature there?

Scuderi - direct

:05:45 1 A. Yes, it is.

:05:47 2 Q. March 17, 1998. Correct?

:05:50 3 A. Yes.

:05:51 4 Q. And just generally speaking, what did this agreement  
:05:57 5 provide for you?

:05:59 6 A. It was a royalty agreement with Zimmer for the design  
:06:06 7 development of a High-Flex implant, both fixed and  
:06:10 8 mobile-bearing.

:06:10 9 Q. Now, there came a time that this agreement was  
:06:19 10 replaced by another agreement. Correct?

:06:22 11 A. Yes.

:06:22 12 Q. And that's what we call the flex royalty resolution  
:06:26 13 agreement. Correct?

:06:27 14 A. Yes.

:06:27 15 Q. Do you know why this agreement -- by the way, as long  
:06:35 16 as I have asked you that question, let's go to PTX-35, if we  
:06:41 17 might?

:06:42 18 That exhibit is the royalty resolution agreement  
:06:54 19 that's at issue in this case. Do you have it there?

:07:00 20 A. Yes.

:07:01 21 Q. And if you turn to Page 23378, is that your signature?

:07:16 22 A. Yes.

:07:16 23 Q. And this agreement was entered into in  
:07:22 24 November-December of 2008. Correct?

:07:26 25 A. Yes.

Scuderi - direct

:07:26 1 Q. Now, do you know why it became necessary for the  
:07:34 2 license and consulting agreement to be replaced with the  
:07:38 3 royalty resolution agreement?

:07:42 4 A. It was told to me that as part of an arrangement  
:07:47 5 federal government, the federal prosecution agreement, that  
:07:51 6 the contracts would be resolved.

:07:54 7 Q. Had a time come when Zimmer actually had stopped  
:07:59 8 making payments under the original license and consulting  
:08:04 9 agreement?

:08:04 10 A. Yes.

:08:04 11 Q. All right. Now, in the royalty resolution agreement,  
:08:15 12 among other things, you received a lump-sum cash payment.  
:08:21 13 Correct?

:08:21 14 A. Yes.

:08:21 15 Q. And that's reflected in Paragraph (A))?

:08:30 16 A. Yes.

:08:30 17 Q. And that amount was \$4,583,146. Correct?

:08:37 18 A. Yes.

:08:37 19 Q. Do you know what portion of that related to moneys  
:08:45 20 that were past due and what portion of it related to  
:08:50 21 discounted future royalties, roughly?

:08:54 22 A. You know, I don't recall.

:08:55 23 Q. For what period of time had you been paid royalties  
:08:59 24 when you entered into this agreement?

:09:02 25 A. From about 2007 onward.

Scuderi - direct

:09:04 1 Q. So roughly two years?

:09:07 2 A. Roughly.

:09:07 3 Q. So as you understood it, that amount included what was  
:09:12 4 owed to you prior to the time the agreement was signed and  
:09:14 5 some calculation of what would have been due in the future?

:09:17 6 A. That's correct.

:09:18 7 Q. Okay. Now, before I go further with this agreement,  
:09:25 8 in the event we are successful before this Court in having  
:09:30 9 this agreement rescinded and set aside, are you prepared to  
:09:33 10 return to Zimmer the sum of \$4,583,146?

:09:39 11 A. Yes.

:09:39 12 Q. Now, was there any provision of this agreement, the  
:09:52 13 royalty resolution agreement, that was actually most  
:09:55 14 important to you?

:09:58 15 A. The most important portion was the term of the  
:10:02 16 agreement, because the royalty -- was the royalty rate as  
:10:05 17 well as the term.

:10:06 18 Q. I am talking about the royalty resolution agreement.  
:10:10 19 What was it you were most concerned about with the royalty  
:10:14 20 resolution agreement?

:10:19 21 A. I believe that --

:10:23 22 Q. Was it how much you were going to be paid?

:10:27 23 A. It does come down to the amount of money --

:10:30 24 MR. HALES: Objection. There has been a fair  
:10:32 25 amount of that.



Scuderi - direct

1 THE COURT: It was leading, counsel.

2 MR. FRIEDMAN: I can rephrase it if Your Honor  
3 wants.

4 THE COURT: I think you should rephrase it,  
5 counsel.

6 BY MR. FRIEDMAN:

7 Q. Was the amount of money that was to be paid to you  
8 important?

9 A. Yes.

10 Q. Very important?

11 A. Yes.

12 Q. Now, if we go to PTX-38 in its entirety in your  
13 notebook, that actually consists of a variety of documents.  
14 Correct?

15 A. Yes.

16 Q. If we could, go to Page 23431?

17 Now, just give me a moment. I am sorry, 23432.  
18 That doesn't list -- does that list any patents that are  
19 attributable to you?

20 A. It does not.

21 Q. Now, if we go, again, to the original license and  
22 consulting agreement, that was subsequently amended.

23 Correct?

24 A. Yes.

25 Q. Okay. If you would, turn to Page 23433. And what is

Scuderi - direct

:12:33 1 that?

:12:34 2 A. That is an amendment to the agreement.

:12:40 3 Q. And who is Roy Crowninshield?

:12:44 4 A. He was the senior vice president for research and  
:12:47 5 development at Zimmer.

:12:53 6 Q. If you look at the third paragraph, what is Zimmer  
:12:56 7 going to be paying you?

:12:59 8 A. The paragraph states that in consideration of the  
:13:01 9 licenses and rights you grant to Zimmer, Zimmer will pay or  
:13:04 10 cause to be paid to you a royalty of 0.5 percent of net  
:13:09 11 sales of the product specified in the enclosed Appendix A.

:13:13 12 Appendix A lists Zimmer products which are ready  
:13:17 13 to be sold and which incorporate design features and  
:13:21 14 technology to which you contribute.

:13:23 15 Q. So the products that are listed in Appendix A you  
:13:32 16 understood to be very specific products for which you were  
:13:36 17 receiving money because of your contributions to those  
:13:39 18 products?

:13:40 19 A. Yes.

:13:40 20 Q. Now, there was an additional amendment to this  
:13:49 21 agreement. Correct?

:13:51 22 A. Yes.

:13:51 23 Q. And let's turn to 23435. That's yet another amendment  
:13:59 24 to the agreement. Correct?

:14:01 25 A. Yes.

Scuderi - direct

:14:01 1 Q. And what did this amendment to the disagreement add or  
:14:06 2 change?

:14:07 3 A. Again, this changed the implants that would be  
:14:15 4 considered under the agreement.

:14:17 5 Q. And if we look at Attachment A, we see different knee  
:14:27 6 products or components on which you were going to receive a  
:14:32 7 royalty payment. Correct?

:14:33 8 A. Right. As the document had said, that Attachment A  
:14:37 9 lists the Zimmer products which are anticipated to be sold  
:14:40 10 and which incorporate design features and technology to  
:14:43 11 which you contributed.

:14:45 12 Q. And that statement was also true -- was also contained  
:14:53 13 in the first amendment, which was dated July 16, 1998,  
:14:59 14 Page --

:15:01 15 THE COURT: Yes, counsel.

:15:05 16 MR. HALES: I have an objection to leading.

:15:07 17 THE COURT: Yes.

:15:08 18 BY MR. FRIEDMAN:

:15:09 19 Q. Was that statement also found in the --

:15:12 20 THE COURT: I am going to get on you like I got  
:15:14 21 on your colleague in a minute.

:15:16 22 MR. FRIEDMAN: I was very sensitive to that.

:15:18 23 THE COURT: You are not acting like it. You are  
:15:21 24 leading the witness. Come on.

:15:23 25 MR. FRIEDMAN: I am going to change my behavior,

Scuderi - direct

:15:25 1 for sure.

:15:26 2 THE COURT: Appreciate it.

:15:26 3 BY MR. FRIEDMAN:

:15:27 4 Q. I draw your attention to the third paragraph of the  
:15:31 5 first amendment to the agreement, July 16, 1998, which is on  
:15:38 6 Page 23433.

:15:40 7 What language does that contain?

:15:43 8 A. That is similar language to the prior document.

:16:01 9 Q. Now, I would like to just discuss how the calculation  
:16:06 10 was made of the amount of money which you were going to  
:16:14 11 receive, which ended up being that four-plus million.

:16:18 12 This document, which we have marked as PTX-38,  
:16:24 13 in its entirety, has several different types of exhibits.  
:16:28 14 Correct?

:16:29 15 A. Yes.

:16:29 16 Q. How did you receive this document?

:16:34 17 A. I was handed this document.

:16:35 18 Q. Pardon?

:16:37 19 A. I was handed this document by a Zimmer representative.

:16:42 20 Q. Do you remember who that was?

:16:48 21 A. Bob Finley.

:16:49 22 Q. And who is that?

:16:54 23 A. I believe he was a regional vice president for Zimmer  
:16:58 24 at that time.

:16:58 25 Q. Now, this document, if you turn, for example, to Page

Scuderi - direct

:17:03 1 23386, has a financial analysis and valuation model.

:17:10 2 Correct?

:17:11 3 A. That's the title of the page, yes.

:17:13 4 MR. HALES: Your Honor, can I just object to the  
:17:16 5 leading?

:17:16 6 THE COURT: I am sorry. I missed that one.

:17:18 7 MR. FRIEDMAN: I just asked him to turn to a  
:17:20 8 page and tell us what this has.

:17:24 9 MR. HALES: I think it was leading. We are  
:17:27 10 trying to get off the leading questions.

:17:28 11 THE COURT: I think we should be a little  
:17:30 12 meticulous about that.

:17:31 13 Doctor, you know where we are, though?

:17:35 14 THE WITNESS: Yes.

:17:36 15 THE COURT: Let's go.

:17:36 16 BY MR. FRIEDMAN:

:17:37 17 Q. Let's turn to the second page of the financial  
:17:39 18 analysis and valuation model, which is Bates-numbered 23387.

:17:47 19 Did you look at this document when you received  
:17:50 20 it?

:17:52 21 A. Yes.

:17:53 22 Q. What does this document contain, generally speaking?

:18:01 23 A. The entire document contains the analysis from Zimmer  
:18:08 24 and their outside accounting firm as to the terms of the  
:18:13 25 resolution agreement.

Scuderi - direct

:18:14 1 Q. Now, if you go to the fourth line, what does this  
:18:21 2 analysis say about whether you have any issued patents?

:18:27 3 A. It says none.

:18:28 4 Q. If you go to the termination date, what does that say?

:18:36 5 A. August 15th, 2009.

:18:39 6 Q. What would that have been the termination date of?

:18:46 7 A. That would have been the termination date of the  
:18:49 8 contract without any patents.

:18:51 9 Q. And you are referring now to the original license and  
:18:59 10 consulting agreement, which was part of this package that we  
:19:02 11 identified before?

:19:04 12 A. Yes.

:19:04 13 Q. If you, indeed, had been an inventor on a patent that  
:19:15 14 was covered by the agreement, what would the termination  
:19:18 15 date of the original agreement have been?

:19:23 16 A. It would have been for the term of the patent.

:19:26 17 Q. Do you know with respect to the patents that we have  
:19:30 18 talked about in this case what the approximate termination  
:19:35 19 date had been if you had been named as an inventor?

:19:39 20 A. It would have been approximately in 2019-020.

:19:44 21 Q. Another ten or 11 years beyond the original term?

:19:48 22 A. Yes.

:19:48 23 Q. If the analysis had said you were an inventor and that  
:19:59 24 the original agreement extended to 2019 or 2020, would you  
:20:05 25 have accepted the sum of 4 million dollars in payment, as is

Scuderi - direct

:20:12 1 indicated here?

:20:13 2 A. No, I would not.

:20:14 3 Q. And as I asked before, if the Court sets aside this  
:20:22 4 agreement, you will return that amount of money. Right?

:20:25 5 A. Yes.

:20:25 6 Q. Have you been able to determine --

:20:29 7 MR. HALES: Your Honor, a little late, but there  
:20:32 8 is still a lot of leading going on.

:20:33 9 THE COURT: The last question was asked and  
:20:34 10 answered.

:20:35 11 BY MR. FRIEDMAN:

:20:36 12 Q. Have you been able to determine what the correct  
:20:38 13 amount would be under this valuation model if it had shown  
:20:43 14 that you were the owner of a patent and that the termination  
:20:47 15 date was, indeed, August 20, 2019 or 2020?

:20:58 16 A. I have not calculated that.

:20:59 17 Q. What information would you need to be able to  
:21:01 18 calculate that?

:21:02 19 A. I would need to know the sale of the products, I would  
:21:07 20 need to have an accountant evaluate it and go through a full  
:21:10 21 analysis.

:21:11 22 THE COURT: Yes, counsel.

:21:13 23 MR. HALES: Objection to relevance in terms of  
:21:16 24 what the precise numbers are.

:21:20 25 THE COURT: To the extent that you understand

Scuderi - direct

1 the objection, do you have a response?

2 MR. FRIEDMAN: I don't.

3 THE COURT: I don't, either. I will overrule  
4 it. Unless you want to restate it.

5 MR. HALES: I think it's fine, Your Honor.

6 BY MR. FRIEDMAN:

7 Q. Who would have the information that you would need to  
8 determine what, in fact, the valuation would be if you were  
9 listed as a patent owner, and if the termination date were  
10 extended another ten, 11 years or so?

11 A. Zimmer.

12 Q. And you have not -- have you been supplied with that  
13 information?

14 A. I have not.

15 Q. Do you have any view as to whether the amount of  
16 money, with those assumptions, would be materially different  
17 than the 4.5 million dollars?

18 A. It would be different.

19 Q. And how do you know that?

20 A. It would be of greater value because it was a longer  
21 term.

22 Q. Are you able to quantify what the difference would be?

23 A. I would have no way of knowing what the magnitude of  
24 the difference would be. It would be definitely a higher  
25 number.



Scuderi - direct

:22:35 1 Q. Do you believe it would be in the millions of dollars?

:22:38 2 A. Yes.

:22:44 3 Q. Now, just to end, one last question. How would you  
:22:49 4 characterize your current relationship with Zimmer?

:22:53 5 A. I have a very good relationship with Zimmer. I  
:22:55 6 continue to be on their design team, continue to work with  
:22:57 7 them in a very collaborative way, part of their educational  
:23:01 8 program.

:23:01 9 So I think it's a very good relationship.

:23:03 10 Q. Do you have a belief whether in 2008, when the royalty  
:23:11 11 resolution agreement was signed, Zimmer had believed that  
:23:16 12 you should have been an inventor on any patents?

:23:20 13 A. I believe they did not know at that time.

:23:22 14 Q. All right.

:23:23 15 MR. FRIEDMAN: I have no further question, Your  
:23:25 16 Honor.

:23:25 17 THE COURT: Counsel, you may cross-examine.

:23:29 18 MR. HALES: Thank you, Your Honor. If I can  
:23:31 19 have one moment.

:23:32 20 THE COURT: Sure.

:24:25 21 CROSS-EXAMINATION

:24:26 22 BY MR. HALES:

:25:03 23 Q. Good afternoon, Dr. Scuderi.

:25:06 24 A. Good afternoon.

:25:06 25 Q. My name is Bryan Hales. I don't think we have

Scuderi - cross

:25:08 1 actually personally met before today. Nice to meet you.

:25:12 2 A. Same here.

:25:12 3 Q. I wanted to follow up on some of the questions that  
:25:16 4 you were asked about the boxes that were in your house.

:25:21 5 A. Okay.

:25:21 6 Q. Now, if I understood the testimony you gave, when Dr.  
:25:27 7 Insall passed away, you were provided with some of his  
:25:30 8 documents?

:25:34 9 A. When Dr. Insall passed away, at that point I was not  
:25:38 10 handed any of his documents. Those documents, one, as his  
:25:44 11 wife came in, cleared out his office, took whatever files  
:25:47 12 that she deemed relevant, were removed upon his passing.  
:25:51 13 Everything else was boxed up, you know, put in a closet.

:25:56 14 Q. That was put in a closet at ISK?

:25:58 15 A. That is correct.

:25:58 16 Q. Those stayed at ISK in that closet until approximately  
:26:04 17 when? Was that 2004?

:26:06 18 A. In 2004 when we relocated the office.

:26:09 19 Q. When you relocated the office, is that when they were  
:26:12 20 handed to you?

:26:14 21 A. No. When the office was relocated it went to a  
:26:17 22 custodial account, a storage facility, for a duration of two  
:26:21 23 years.

:26:21 24 Q. Then at the end of that two years is when you had the  
:26:24 25 documents and put them under your desk. Is that correct?

Scuderi - cross

:26:26 1 A. That is correct, some of the boxes, yes.

:26:29 2 Q. So you received boxes in 2006 that were Dr. Insall's  
:26:33 3 materials and put them under your desk?

:26:35 4 A. Well, they were commingled with mine, because again,  
:26:38 5 it was part of research files and a lot of the material, we  
:26:42 6 shared secretarial staff, and as they boxed everything,  
:26:44 7 there were some files that were obviously commingled. Those  
:26:48 8 boxes ultimately, because they were just labeled, were put  
:26:52 9 on my desk.

:26:54 10 Q. The materials in those boxes by that point did not  
:26:58 11 have personal effects of Dr. Insall, as you would  
:27:01 12 understand, because Mrs. Insall had come and removed that  
:27:04 13 type of information?

:27:05 14 A. That's correct.

:27:06 15 Q. Now, you eventually, I think, said you took those  
:27:12 16 boxes out from under your desk and took them to your house?

:27:15 17 A. Correct.

:27:16 18 Q. During the time that they were in your office under  
:27:19 19 your desk, you had access to them. That's fair to say?

:27:22 20 A. They were sitting under my desk. I never opened them.  
:27:25 21 I just left them there.

:27:26 22 Q. You could have?

:27:27 23 A. I know I didn't.

:27:28 24 Q. You could have opened them?

:27:32 25 A. I know I didn't open those boxes. They just sat under

Scuderi - cross

:27:36 1 my desk collecting dust.

:27:38 2 Q. My question is relatively simple, Dr. Scuderi. You  
:27:42 3 could have opened the boxes as they sat under your desk?

:27:45 4 A. If I had a reason to I could have. There wasn't a  
:27:49 5 lock and key.

:27:49 6 Q. There was not a lock and key there?

:27:51 7 A. Right.

:27:51 8 Q. You moved them to your basement and garage, and/or  
:27:56 9 garage eventually. When did that happen?

:27:58 10 A. I don't remember specifically. It was sometime  
:28:00 11 between 2006, 2009. I am going to say probably within a  
:28:05 12 year or so, as boxes started to accumulate under my desk,  
:28:08 13 just for convenience, I moved them out.

:28:11 14 Q. And during the time they were at your house and your  
:28:14 15 garage, again, you had access to the materials in them.  
:28:17 16 Correct?

:28:18 17 A. Similar response as before. Yes.

:28:20 18 Q. The response being ultimately that you could have  
:28:22 19 opened them and seen what's in them if you wanted to.  
:28:25 20 Correct?

:28:25 21 A. If I wanted to, yes.

:28:26 22 Q. Now, eventually, you looked at them in connection with  
:28:31 23 this case. Correct?

:28:34 24 A. Yes.

:28:34 25 Q. And was that for production in this case?

Scuderi - cross

:28:39 1 A. Simultaneously, I have a lot of my own boxes and files  
:28:41 2 and they were sitting amongst a pile of things. So I went  
:28:45 3 through my boxes, those boxes, and, yes, it was production  
:28:49 4 and material for this case.

:28:50 5 Q. Did you also look through those boxes during the  
:28:52 6 period of time that you were looking for information to  
:28:57 7 support your involvement in the Gender development? Do you  
:29:02 8 know what I am talking about?

:29:03 9 A. Yes. I know what you are talking about.

:29:05 10 Q. Did you look through those boxes at that time?

:29:08 11 A. Not those specific boxes for the Gender material. The  
:29:12 12 Gender material had been stored in my office in a separate  
:29:17 13 file.

:29:17 14 Q. Now, at any point during the discussions about Gender,  
:29:24 15 did you ever suggest to Zimmer that information relating to  
:29:27 16 your flex work was also related to your Gender  
:29:30 17 contributions?

:29:33 18 A. I know I had discussions with Zimmer when we were  
:29:35 19 resolving the Gender agreement that the components on Gender  
:29:40 20 were similar to LPS Flex. I did have conversations with  
:29:45 21 Zimmer at that time.

:29:46 22 Q. And therefore, some of your work on those Flex  
:29:49 23 components was relevant, in your view, to demonstrating your  
:29:53 24 contributions to the Gender components. Correct?

:29:55 25 A. So the material that I provided to Zimmer to support

Scuderi - cross

:29:58 1 my contributions to Gender, again, was in a separate folder,  
:30:03 2 in a separate location. And that material was sufficient in  
:30:07 3 our discussions to try to work through the royalty  
:30:10 4 resolution agreement on the Gender project.

:30:12 5 Q. That wasn't my question. My question was, the work  
:30:16 6 that you did on Flex, in your view, was relevant to the  
:30:20 7 contributions that you made to the Gender project?

:30:22 8 A. The answer to that question is yes then.

:30:24 9 Q. Now, this investigation that you undertook regarding  
:30:32 10 these documents, that happened, as I understand, in the last  
:30:35 11 24 hours or so. Is that correct?

:30:41 12 A. The boxes, yes, just to clarify a point, yes.

:30:47 13 Q. That happened, I take it, after openings began in this  
:30:51 14 case, openings happened?

:30:55 15 A. No. It happened prior to openings.

:30:57 16 Q. Prior to openings. So would that be Monday morning?

:31:01 17 A. Actually, the conversation was Sunday night.

:31:02 18 Q. Sunday night?

:31:03 19 A. Yes.

:31:03 20 Q. So Sunday night, the conversation with your counsel, I  
:31:09 21 presume, prompted you to go and do this investigation about  
:31:12 22 these boxes?

:31:13 23 A. Yes.

:31:13 24 Q. Now, the investigation, I think you mentioned, you  
:31:17 25 needed to talk to some secretaries or assistants and so

Scuderi - cross

:31:20 1 forth?

:31:21 2 A. Yes.

:31:21 3 Q. The fact is that a significant part of this  
:31:26 4 explanation you have given is that the documents were in  
:31:29 5 your possession the whole time. Correct?

:31:32 6 A. Yes.

:31:32 7 Q. Under your desk, you put them there, you moved them to  
:31:36 8 your house. Correct?

:31:38 9 A. Yes.

:31:38 10 Q. I want to follow up on some of the documents that Mr.  
:31:48 11 Friedman used with you during your examination. If we can  
:31:51 12 turn to PTX -- or put up, Mr. Smith, PTX-176?

:31:58 13 Dr. Scuderi, I think you should have that before  
:32:03 14 you still in the binder Mr. Friedman provided. This is the  
:32:11 15 overview, where you were asked a few questions on direct  
:32:18 16 examination?

:32:18 17 A. Yes.

:32:18 18 Q. Your attention was called to the second -- I guess the  
:32:21 19 third page of the document, the page numbered 2 in the lower  
:32:25 20 right, which identifies the developing surgeons called out  
:32:29 21 as Dr. Insall, Dr. Scuderi, and Dr. Kelly. Do you see that?

:32:32 22 A. Yes.

:32:33 23 Q. Now, Dr. Scott is not listed in this document. Is  
:32:36 24 that correct?

:32:37 25 A. That's correct.

Scuderi - cross

:32:37 1 Q. Now, you actually saw a draft of this document prior  
:32:41 2 to this version. Is that true?

:32:54 3 A. I don't recall.

:32:56 4 Q. Dr. Scuderi, in the binder I have now handed you,  
:34:07 5 could you turn to Defendants' Trial Exhibit 136?

:34:13 6 A. Yes.

:34:16 7 Q. Let me know when you have gotten there?

:34:39 8 A. I am seeing 131, 137. I am not seeing 136.

:34:49 9 THE COURT: I don't see it, either, counsel.

:34:51 10 Okay, you have it.

:35:10 11 MR. HALES: May I approach again, Your Honor?

:35:13 12 THE COURT: Yes, you have free leave to do that.

:35:15 13 BY MR. HALES:

:35:16 14 Q. You now have, Dr. Scuderi, Defendants' Trial Exhibit  
:35:28 15 136?

:35:28 16 A. Yes.

:35:29 17 Q. And this is dated about a month before Plaintiffs'  
:35:37 18 Trial Exhibit 176. Correct?

:35:38 19 A. Yes, 20 days, yes.

:35:41 20 Q. And that attaches a draft of the Gemini Project  
:35:46 21 document that is in the exhibit Mr. Friedman used with you.  
:35:50 22 Correct?

:35:51 23 A. Yes.

:35:51 24 Q. And it asks you in the cover letter, or indicates that  
:36:00 25 they are sending you a draft. Correct?



Scuderi - cross

:36:11 1 A. Yes.

:36:12 2 Q. Now, the same surgeons, if you look at Page 2 of the  
:36:19 3 document again, Dr. Insall, Dr. Scuderi and Dr. Kelly, are  
:36:23 4 listed there?

:36:24 5 A. Yes.

:36:25 6 Q. Now, I didn't see anything in the record where you  
:36:35 7 indicated back to Zimmer that they should add Dr. Scott to  
:36:39 8 this agreement. Is that fair?

:36:40 9 A. That is correct.

:36:40 10 Q. You don't recall doing that, do you?

:36:43 11 A. I do not.

:36:43 12 Q. Now, Mr. Friedman also used Plaintiffs' Trial Exhibit  
:36:54 13 203 with you. I would ask you to turn back to that, if you  
:36:58 14 would.

:37:17 15 A. I have it.

:37:18 16 Q. You remember this e-mail that you were asked questions  
:37:23 17 about by Mr. Friedman?

:37:25 18 A. Yes.

:37:25 19 Q. This is internal to Zimmer, is that correct, this  
:37:28 20 e-mail?

:37:31 21 A. Yes.

:37:31 22 Q. So you have not seen it before this case, I take it?

:37:36 23 A. It was provided to us during discovery of this case,  
:37:39 24 yes.

:37:39 25 Q. Now, in the document, there is no mention of anything

Scuderi - cross

:37:46 1 that is attributed to either you or Dr. Scott. Is that  
:37:50 2 correct?

:37:51 3 A. The document relates to a cadaver lab at ISK. That  
:37:57 4 cadaver lab would have been conducted by myself with Dr.  
:38:00 5 Insall and Dr. Scott. At that point Dr. Insall had been  
:38:03 6 ill, and I know we had been with him quite routinely.

:38:06 7 Q. But the document records observations of Dr. Insall at  
:38:12 8 the meeting that you say all three of you were at. Correct?

:38:15 9 A. It's an internal document that states exactly what you  
:38:18 10 said. However, you know, realistically, that was a cadaver  
:38:22 11 lab at the ISK Institute similar to all other cadaver labs  
:38:26 12 we, Dr. Scott, Dr. Insall and I were there.

:38:30 13 Q. I understand your testimony that you were there. What  
:38:32 14 I am asking about is, if you look, for example, under  
:38:34 15 Cadaver Observations, Paragraph 3, in the third-to-last line  
:38:37 16 it says, Dr. Insall suggested steps to be taken, et cetera.  
:38:42 17 Do you see that?

:38:43 18 A. I do.

:38:43 19 Q. And then under the Cadaver Observations category,  
:38:47 20 that's the only reference to somebody making that comment or  
:38:52 21 observation that's by name. Is that fair?

:38:54 22 A. That's the only name mentioned.

:38:56 23 Q. If we look at the meeting minutes portion of the  
:38:59 24 document, which is below, it starts at the bottom of the  
:39:02 25 first page, Item 1, you see that, Dr. Insall immediately

Scuderi - cross

:39:06 1 eliminated the shorter .275 high trunnion, et cetera? Do  
:39:10 2 you see that?

:39:11 3 A. Yes.

:39:11 4 Q. Paragraph 2. Dr. Insall agreed to allowing a hole to  
:39:16 5 go through the nine-millimeter thick polys. Do you see  
:39:20 6 that?

:39:21 7 A. Yes.

:39:21 8 Q. Paragraph 3, Dr. Insall stated that the thicker  
:39:24 9 articular surfaces were likely to go, et cetera, et cetera.  
:39:27 10 Do you see that?

:39:28 11 A. Yes.

:39:28 12 Q. Dr. Insall, in Paragraph 4, shared his concerns that  
:39:31 13 the LPS mobile did not visually appear, et cetera?

:39:34 14 A. I see that.

:39:35 15 Q. And Paragraph 5, Dr. Insall had two suggestions, to  
:39:39 16 reduce the likelihood of articular surface spinout, et  
:39:43 17 cetera?

:39:43 18 A. I see that.

:39:44 19 Q. So the only comments attributed to a specific  
:39:48 20 individual in the document are to Dr. Insall?

:39:51 21 A. That's what the document states. It may not be the  
:39:54 22 reality.

:39:55 23 Q. But you don't have any documentary evidence to the  
:39:58 24 contrary. Correct?

:39:59 25 A. It was a cadaver lab done at the ISK Institute. We

Scuderi - cross

:40:02 1 coordinated the cadaver lab. Dr. Insall would not have  
:40:05 2 coordinated that cadaver lab without us being there, without  
:40:08 3 me setting that up and getting the body parts.

:40:10 4 Q. Fair enough. But you don't have any documentary  
:40:13 5 evidence of contributions, observations, suggestions, either  
:40:17 6 you or Dr. Scott made at the lab?

:40:20 7 A. You know, similar to what I said earlier. This was  
:40:23 8 always a collaborative process. Again, Dr. Insall, Dr.  
:40:26 9 Scott and myself were always collaborating on these issues,  
:40:29 10 these ideas, these concepts. The records are reporting Dr.  
:40:32 11 Insall. But again, as our most senior surgeon, senior  
:40:37 12 partner, who actually was ill at the time, diagnosed with  
:40:40 13 cancer, we were there to help and support him and again  
:40:43 14 support him and collaborate with him throughout the process.

:40:47 15 Q. I understand that he was ill. But it seems like he  
:40:51 had an awful lot of useful things to say at the meeting?

:40:55 A. John always had a lot of useful things to say. Again,  
:40:58 it was a collaborative process. They are reporting very  
:41:01 clearly that Dr. Insall said, he identified five features.  
:41:06 Again, that is part of the collaborative process.

:41:08 Q. Okay. Let's turn to PTX-135, another document that  
:41:13 you were examined about during Mr. Friedman's direct.

:41:36 A. I have it.

:41:36 Q. This was a document that was produced by you and Dr.  
:41:38 Scott in this litigation. Correct?

Scuderi - cross

:41:40

A. Yes.

:41:40

Q. And you know that because of the S&S Bates number in the lower right corner. Right?

:41:45

A. That's correct.

:41:48

:41:48

Q. This is a letter that is from 1997 from Mark Heldreth to Dr. Insall. Correct?

:41:53

:41:54

A. Yes.

:41:57

Q. You were not a recipient, copy, or otherwise of this document. Correct?

:42:01

:42:02

A. I was a recipient of this letter because it was handed to me by Dr. Insall.

:42:04

:42:06

Q. And that was about the time that you received it?

:42:08

A. Correct.

:42:08

Q. Now, it wasn't sent to you?

:42:13

A. Correct.

:42:13

Q. So it was received by you if Dr. Insall handed it to you. Correct?

:42:17

:42:18

A. That is correct.

:42:19

Q. Now, in the document there is no reference to specific contributions by you or Dr. Scott. Is that fair to say?

:42:31

:42:34

A. We are not mentioned in that particular letter.

:42:37

Q. Let's take a look at Plaintiffs' Trial Exhibit 189. Just let me know when your there.

:42:46

:42:55

A. Okay.

:42:55

Q. This is a document that Mr. Friedman asked you

Scuderi - cross

:42:58 questions about again during direct examination. Do you  
:43:00 recall that?

:43:00 A. Yes.

:43:01 Q. I think one of the things you testified about, about  
:43:05 this meeting, was that Dr. Scott was in attendance at the  
:43:09 meeting that is described in this memo. Correct?

:43:11 A. Yes.

:43:11 Q. Now, you have no documents that corroborate that. Is  
:43:19 that fair?

:43:22 A. Dr. Scott's name was not listed on the distribution or  
:43:27 the attendance list. But as our standard practice was, he  
:43:31 would be at the cadaver lab because it was at the institute.

:43:34 Q. But my question is, you don't have a document that  
:43:37 supports that claim. Correct?

:43:40 A. I don't see his name listed there. And it's my  
:43:44 recollection that he was there.

:43:45 Q. There is no other document about this meeting in the  
:43:48 record that we have anywhere that indicates, for example,  
:43:50 that Dr. Scott was there?

:43:52 A. I don't know of any other document for that particular  
:43:55 meeting.

:43:56 Q. For example, there is not notes for any of the  
:44:00 meetings we have looked at thus far in these few documents,  
:44:03 you don't have, neither you nor Dr. Scott nor ISK doesn't  
:44:08 have its own set of notes pertaining to those meetings.

Scuderi - cross

Right?

A. No, as I said earlier, we did not keep any formal notes.

Q. So the records we have available on this issue are the records we are looking at that were from Zimmer?

A. These are the records provided by Zimmer.

Q. So if we go -- and you alluded to this -- if we go to the second page of this document, it's got a distribution list. Correct?

A. Yes.

Q. Dr. Scott is not identified in the distribution list. Correct?

A. Correct.

Q. Now, it goes further, and below the distribution list, notes by asterisks, indicates by asterisks denotes those attending the meeting. Correct?

A. Correct.

Q. So the distribution was broader than the meeting attendees. Correct?

A. There is more names on the distribution list.

Q. Now, if we look at the contents of Plaintiffs' Trial Exhibit, 189. Under the fixed-bearing option, I am on Page 1, second paragraph, there is a reference to Dr. Insall having, feeling that the jump height with the modified cam approach, et cetera. Do you see that?

Scuderi - cross

A. Yes.

Q. Now, in the second paragraph there is a reference to you and Dr. Insall having a comment. Correct?

A. Yes.

Q. In the paragraph under Micromotion, you and Dr. Insall are noted there. Correct?

A. Yes.

Q. Turn to the next page, we can spare some time, if we go to the next page, it's always references to either you or Dr. Insall. Correct?

A. Yes.

Q. Nowhere do we see a reference to Dr. Scott making media comment, observation, contribution. Correct?

A. I do not see his name.

Q. So if he was there, there is no indication that he said anything?

A. Nothing that was recorded by, I believe it was Mark Heldreth who drafted the document.

Q. Now, the other thing about this document is the date, July 16th, 1998. Do you know how that date compares to the filing date of the applications that led to the '729 and '786 patent?

A. The filing for '729 is March 10th, 1998.

Q. Now, there were a few questions about the NexGen PS, and problems that it had, and the NexGen LPS, which was the



Scuderi - cross

redesign. Do you recall that?

A. Yes.

Q. ISK was involved in the design of the NexGen PS.

Correct?

A. The NexGen PS was a collaborative process with multiple design surgeons.

Q. Including those from ISK?

A. Yes.

Q. Now, do you remember the three particular patients of which you observed radiolucencies?

A. I don't remember the names of the patients.

Q. Not the names, but do you remember the fact?

A. I remember the fact there were radiolucencies.

Q. Do you know if those patients were revised or not around that time?

A. I have no recollection of the clinical outcome of the patients in question.

Q. I am going to turn now to your license agreement and release agreement that you were asked some questions about.

DTX-137, if you could turn to that in the binder that I gave you. Do you have that?

A. Yes.

Q. This is the license agreement for the LPS Flex project?

A. Yes.

Scuderi - cross

Q. And you looked at this, although it was attached to another document and I am using it on its own, but this document is signed by you on the third to last page.

Correct? DTX-137?

A. Yes.

Q. This agreement was terminated by the royalty resolution agreement that you discussed with Mr. Friedman.

Correct?

A. Yes.

Q. And you already covered by, I will just confirm, if you look at Attachment B, there are no patents listed as part of the license agreement DTX-137. Correct?

A. Correct.

Q. During all the amendments that happened throughout the term of this agreement, that was never amended to add any patents. Correct?

A. Correct.

Q. Now, the royalty payments that you received -- strike that question.

You understood at the time you entered this license agreement, DTX-137, that the payment period, the royalty payment period would be different if there were licensed patents versus not licensed patents. Correct?

A. Correct.

Q. And if there were licensed patents, the payment period

Scuderi - cross

would be through their expiration. Correct?

A. Correct.

Q. And if there were not licensed patents, the payment period would be for ten years of sale, from the first launch of the commercial product. Correct?

A. Correct.

Q. Now, the components that were paid on were the fixed and mobile High-Flex NexGen products. Is that fair?

A. Yes.

Q. And you would agree that the patents at issue in this case, the '729, '786 and '283 patents, you contend, relate to those prostheses?

A. Yes.

Q. Now, there is no provision in the license agreement for payment on a patent to which you claim you should have been named an inventor. Is that fair?

A. One that I should have been, no. But if I was a patentholder on the license, then it would have been included.

Q. Right. I understand your point there. But there is no provision for paying on something that you claim to be an inventor on?

A. I would have to be on the patent.

Q. Now, those characteristics of the payment term you understood when you entered the agreement. Correct?

Scuderi - cross

:51:20 A. Yes.

:51:21 Q. And you understood them, leading up to and as of the  
:51:24 signing of your royalty resolution agreement, December 1st,  
:51:27 2008. Correct?

:51:29 A. I was aware of it, yes.

:51:30 Q. And you understood them?

:51:31 A. Yes.

:51:31 Q. Now, if we could, let's take a look at DTX-76, which  
:51:37 is your royalty resolution agreement.

:51:44 My apologies. Before we get to that, let's take  
:51:46 a look at DTX-128.

:51:49 Do you have that, Dr. Scuderi?

:52:01 A. Yes.

:52:02 Q. DTX-128 is a letter from Zimmer to Zimmer consultants.  
:52:07 Do you see that?

:52:08 A. Yes.

:52:09 Q. And it describes in there this process, it describes  
:52:15 some of the background that leads to the royalty resolution  
:52:17 agreement process. Correct?

:52:18 A. Yes.

:52:19 Q. And it indicates the Department of Justice  
:52:22 investigation at the bottom of the first page and the  
:52:25 deferred prosecution agreement. Do you see that?

:52:27 A. Yes.

:52:27 Q. Did you receive a letter like this?

Scuderi - cross

:52:30

A. Yes.

:52:31

Q. At or about that time, in April 2008?

:52:36

A. Somewhere around that time.

:52:37

Q. You mentioned that your royalties, Zimmer had stopped paying your royalties in about 2007 or so. Right?

:52:40

A. Yes.

:52:44

Q. You understood that that was because of this issue?

:52:44

A. Yes.

:52:47

Q. Now, let's go back to DTX-76. This is the royalty resolution agreement you entered with Zimmer pertaining to the High-Flex product. Correct?

:52:47

:53:07

the High-Flex product. Correct?

:53:10

A. Yes.

:53:14

Q. You were represented by, I believe, Robert Cochran in relation to your negotiations with Zimmer regarding DTX-76?

:53:14

A. Yes.

:53:24

Q. Robert Cochran is an attorney at SNR Denton, one of Mr. Friedman's partners. Correct?

:53:24

A. Yes.

:53:32

Q. You reviewed the agreement before you signed it.

:53:33

Correct?

:53:35

A. Yes.

:53:36

Q. Mr. Cochran reviewed the agreement before you signed it?

:53:36

A. Yes.

:53:42

Q. And you had his advice in connection with the royalty

:53:42

Scuderi - cross

resolution agreement. Correct?

A. Yes.

Q. It was signed, I believe, on December 1st, 2008?

A. No. I actually signed it on November 24th.

Q. Fair enough. You signed it on November 24th. Zimmer signed it on December 1st, 2008. The effective date, if I can call your attention to the very first paragraph, the resolution effective date is December 1st, 2008?

A. Okay.

Q. Correct?

A. Yes.

Q. Now, you looked at the Alex Parker presentation with Mr. Friedman. I have that as DTX-131.

Turn to PTX-38, if you would.

MR. HALES: Your Honor, in order to try to not have two of the same exhibits in there, I will try to go on the fly to where they introduced it.

So PTX-38.

THE WITNESS: Okay.

BY MR. HALES:

Q. So PTX-38 is the Alex Parker presentation. Correct?

A. Yes.

Q. Now, you had identified, if we look at Page 6, it's the Page 6 at the bottom, one more page past that?

Scuderi - cross

:55:43                   You had called out the notation here that there  
:55:48                   are no issued patents?

:55:50           A.       Yes, at that time I had not known that there were  
:55:53           patents on the prosthesis.

:55:55           Q.       But the fact was true at December 31st, 2008, that  
:56:03           there were no issued patents in your name germane to the  
:56:06           license agreement. Correct?

:56:08           A.       That's correct. And I was unaware that there were any  
:56:10           patents on the LPS fixed or flex mobile-bearing implant.

:56:15           Q.       But that fact is true in the Alex Parker presentation  
:56:19           as of the time it was given to you. Correct?

:56:21           A.       It's listed that I have no patents on the document.  
:56:24           As I said, I was totally unaware that there were any patents  
:56:28           issued on LPS. If I had known, it would have been a  
:56:32           different scenario.

:56:33           Q.       You had no patents issued in your name at that time  
:56:37           pertaining to this agreement. Correct?

:56:38           A.       On the LPS Flex or the LPS Flex mobile, correct.

:56:41           Q.       Today you have no patents issued in your name  
:56:45           pertaining to this agreement or LPS Flex or mobile.  
:56:47           Correct?

:56:47           A.       Correct. That's why we are here.

:56:49           Q.       Now, the payment that you received of four and a half  
:56:59           million dollars, approximately, you received that payment.  
:57:02           Correct?

Scuderi - cross

A. Yes.

Q. Now, you haven't returned that payment to Zimmer, have you?

A. I have not.

Q. You haven't tendered it to Zimmer, have you?

A. I have not.

Q. You have never offered to Zimmer, "I don't believe this agreement is in force, please take my money back"?

A. I have not.

Q. Or, "The money that you made me as part of this agreement, please take it back because I believe the agreement should be rescinded"?

A. I have not made that offer.

Q. When you received the four and a half million dollars, you were dissatisfied with the amount of payment. Is that fair?

A. I was dissatisfied once I had learned that there were patents issued on the implant.

Q. Well, in fact, isn't it true that you were dissatisfied with the payment before you claim to have learned about the patents pertaining -- to the patents at issue?

A. I was not dissatisfied until I learned about the patents at issue.

Q. Let me have Dr. Scuderi's deposition.



Scuderi - cross

:58:10 Dr. Scuderi, I have handed you a copy of the  
:59:05 deposition that you gave in this proceeding. Do you see  
:59:07 that?

:59:07 A. Yes.

:59:07 Q. Do you recall being deposed?

:59:09 A. Yes.

:59:09 Q. And you were under oath at the time?

:59:11 A. Yes.

:59:11 Q. I take it you testified truthfully at the time?

:59:15 A. Yes.

:59:15 Q. Now, I want to direct your attention to Page 246,  
:59:24 Lines 9 through 14. Please let me know when you have had a  
:59:42 chance to review that segment.

:59:52 A. Yes.

:59:53 Q. The question asked there is "Prior to when you  
:59:57 allegedly learned about the patents in or around March of  
:59:59 2009, were you dissatisfied with the payment that you  
:00:02 received under your Flex royalty resolution agreement?

:00:05 "Answer: Yes, because if I was -- yes."

:00:09 Do you see that?

:00:11 A. I see that.

:00:12 Q. Was that truthfully given at the time?

:00:14 A. You know, I think if we go back to the question before  
:00:19 that, I think that is -- once you learned about the patents  
:00:23 and the implication of the patents being identified as

Scuderi - cross

:00:25 inventor, yes, and that related to a question similar to  
:00:30 that.

:00:31 Prior to that were you dissatisfied?

:00:35 My dissatisfaction centered around the time of  
:00:39 the identification of the patents on or around March of  
:00:44 2009. That's what ultimately my truthful testimony is.

:00:48 Q. What was asked then, just to be clear, was prior to  
:00:52 when you allegedly learned about -- that's the question we  
:00:54 covered. Is that correct?

:00:55 A. That's what the followup question was. It does say,  
:00:59 yes. But, you know, again, it relates back to my former  
:01:03 response. You know, obviously, there was a little bit of  
:01:09 dialing bantering back and forth between the attorneys and  
:01:12 myself.

:01:12 Q. Isn't it true that you believe as part of the Flex  
:01:15 royalty resolution agreement you were accepting a reduced  
:01:17 payment compared to what you were entitled?

:01:20 A. Yes, that was part of the calculation, yes.

:01:22 Q. So as of the signing of the royalty resolution  
:01:25 agreement, and this is before you discovered the patents,  
:01:28 allegedly, but as of the signing, you believed that you were  
:01:31 accepting a reduced royalty payment?

:01:34 A. I was accepting a reduced royalty payment, because it  
:01:36 was a discounted variable that was factored into it. If it  
:01:40 had gone to term, obviously, that would have been a higher

Scuderi - cross

payment.

Q. The discount variable was to calculate the net present value of future royalty streams. Correct?

A. Correct.

Q. Now, if we go back to Defendants' Exhibit 76.

Go ahead and go to that. As we are going there, you had also received royalties prior to the first quarter of 2005 on LPS Flex products. Correct?

A. I had received prior royalty payments.

Q. Do you know approximately how much you had received from launch until 2005?

A. No, I do not.

Q. In the millions?

A. Yes.

Q. Now, back on DTX-76, sir, I should say PTX -- I am sorry, DTX-76 is the way -- 35. PTX-35. Sorry.

A. PTX-35?

Q. Yes.

A. Okay.

Q. I am trying to avoid confusion, but I seem only to be confusing myself.

All right. So we are on the royalty resolution agreement. Now, at the introduction there is a series of Whereas clauses. Do you see that?

A. Yes.

Scuderi - cross

Q. And the first "Whereas" clause refers to a license agreement. You would agree that that is the Flex license agreement?

A. Yes.

Q. And you agreed, and you see down at the end of the introduction the Now Therefore clause. Do you see that?

A. Yes.

Q. In it the parties agreed that they acknowledged the receipt and sufficiency of the consideration provided under the agreement. Correct?

A. Yes.

Q. And you understood that one of the purposes of this agreement was to terminate the Flex license agreement. Correct?

A. Yes.

Q. And you understood that that was important, that it be ended, because of the situation with the Department of Justice and Zimmer's monitor. Correct?

A. As I was told, the reason for this resolution, Zimmer was told by the monitor to terminate these agreements. That is what I was led to believe.

Q. You understood, I take it, that that was an important provision for Zimmer. Correct?

A. Yes.

Q. And in the "Whereas" clause, in fact, the third one

Scuderi - cross

indicates that the agreement and Zimmer's decisions have been reviewed and not objected to by its federally selected monitor. Correct?

A. Correct.

Q. If we could take -- well, very quickly, Paragraph 3 is where the termination is provided for. Is that right?

A. Yes.

Q. That is the termination of the Flex license agreement?

A. Yes.

Q. Now, if we could also take a look back one page at Section 2(C). Another aspect of the agreement that you entered in 2(C) is stated here. The payment amount set forth in Section (A) extinguishes in total Zimmer's payment obligations to licensor under the license agreement, including any and all compensation or remuneration paid to, owed to, et cetera?

Do you see that?

A. Yes. And it was my understanding that related to the last part, any outstanding, you know, expenses, services, professional services, meals, travel, medical education.

Q. It was your understanding that only related to those?

A. Yes. It goes on, royalty or other payments for the transfer of intellectual property.

Q. You would agree that the payment as set forth in Section (A), which was 4.5 million dollars, roughly, is

Scuderi - cross

stated here to extinguish in total Zimmer's payment obligations to licensor under the agreements?

A. Yes. And it was my understanding at that time, too, because of the fact that I had not known about the patents, that that's what it was intended. Once I learned about the patents, that was a completely different viewpoint.

Q. Now, during the development work -- well, let me withdraw that question. You never told Zimmer that you should be a -- you should have been named as an inventor on the '729, '786, or '283 patents. Correct?

A. I had never known to tell anyone about that. I had not known that the patents were being applied, that there was any patent process going on at that point in time. If I had known earlier during that period of time, I definitely would have spoken up.

Q. Now, you didn't look into whether you might be due more money under the royalty resolution agreement before signing it. Correct?

A. No. At that point again, as I mentioned earlier, I knew of no patents that were in existence related to the High-Flex fixed or mobile-bearing implant that would have impacted the resolution agreement.

Q. But you didn't look into seeing if they were part of the negotiations leading up to signing it. Corrects?

A. The answer is, no, I did not. Any information about

Scuderi - cross

:07:48 patents would have been expressed to me by Zimmer, a  
:07:53 designed consultant, a design surgeon, a design consultant,  
:07:57 any patents issued, I would be aware of it. Whether I was  
:07:59 on it or not would give me the opportunity to challenge it,  
:08:02 if I had known about it.

:08:03 Q. Or perhaps, also, if Dr. Insall believed that you had  
:08:07 contributed to the initial conception he might have alerted  
:08:10 you to the fact that there were patents being applied for?

:08:13 A. I am really surprised about that. I would not have  
:08:16 expected -- I would have expected that I would have been  
:08:19 named based upon the collaborative process, you know,  
:08:22 unfortunately, Dr. Insall got sick right around the time  
:08:24 that the patents were being filed. I am not sure about the  
:08:28 due process.

:08:32 Q. He wasn't sick at the time you sent the fax to Audrey  
:08:36 Beck in 1995. Was he?

:08:38 A. No. But again, that fax and that drawing, that was a  
:08:41 drawing that was very similar to the drawings that we had  
:08:44 when I testified in April. I was very surprised that  
:08:48 document went to Audrey without our knowledge.

:08:50 Q. Let's be clear on the issue I am trying to focus on.  
:08:53 You are not going to say it was Zimmer's fault entirely that  
:08:57 you didn't know about these patents. Correct?

:08:58 A. No. I think again, it's -- I am going to say it's a  
:09:03 mutual mistake.

Scuderi - cross

Q. So you are not accusing Zimmer of having withheld information from you during the negotiations. Correct?

A. During the negotiations, I am not accusing Zimmer of that.

Q. Now, once you did look for patents, they were rather easy to find. Is that correct?

A. Yes.

Q. You found them, as I understand, by getting on Google patents and pulling them up. Correct?

A. That's correct.

Q. The LPS Flex agreement, the original license agreement, was not your only agreement with Zimmer. Is that correct?

A. That's correct.

Q. You also have an agreement with Zimmer relating to the Gender project. Correct?

A. Yes.

Q. You entered a royalty resolution agreement pertaining to the Gender license agreement as well. Correct?

A. Yes.

Q. And I think you understood that Zimmer's monitor, the federally appointed monitor, had voiced concerns about your level of involvement in the Gender project. Is that correct?

A. Yes.



Scuderi - cross

Q. And as a result of that, the monitor wasn't going to approve a payment of the full expected value of your Gender license agreement. Is that right?

A. That's correct.

Q. And I think you had -- this might have in part been because you had joined the Gender team after the design freeze. Is that correct?

A. I was led to believe that it was related to an earlier meeting that occurred just prior to my signing the Gender agreement. I am not sure about the designing freeze date relative to my signing of that agreement.

Q. One of the things that you did -- well, strike that.

I take it you weren't happy to hear that you were not going to be paid -- or the potential was that you would not be paid full value for the Gender agreement. Correct?

A. Correct. I was very unhappy about that at that time.

Q. And I think you went and looked for information to help support and document your involvement in the Gender project to show it was more than the monitor was giving you credit for. Correct?

A. That's correct, because it was a very substantially discounted payment.

Q. At the end of the day, was there a discount in place in your Gender resolution agreement?

Scuderi - cross

A. It was still a very reduced resolution.

Q. And you were unhappy about that, you remained unhappy?

A. Well, you know, when one thing should be compensated at a higher value, the answer is, yes, you would be dissatisfied. I tried to work it out, and we worked it out partially but not completely.

Q. And that dissatisfaction is one of the factors that led you to scrutinize the patent issue that brings us here today?

A. That was part of what brought it to my attention, that I needed to look into this a lot further. I needed to find out why this had occurred and then to scrutinize the LPS Flex and fix-bearing resolution agreement.

Q. I want to go back to your claim for the rescission of the resolution agreement again.

You are asserting, and we covered this a little bit, just to recap, you are asserting it should be rescinded on the basis of mistake. Correct?

A. Yes.

Q. The only mistake that you are asserting is the alleged mistake that you were not named as an inventor on the patents, or that you should have been named as an inventor on the patents?

A. Yes.

Q. Now, the issue of should you have been named on a

Scuderi - cross

:12:59 patent never came up at all during your discussions with  
:13:02 Zimmer. Is that fair?

:13:03 A. It's because I had not known about the patents. If I  
:13:06 had known about the patents at that time, yes, I would have  
:13:10 then challenged the resolution agreement.

:13:12 Q. So the answer to my question is, it's correct, the  
:13:14 issue never came up at all?

:13:16 A. The issue did not come up at all initially.

:13:33 Q. You are not aware of any Zimmer products that are  
:13:39 covered by the '786 patent. Is that correct? That's the  
:13:42 one with the modular buildup of the posterior condyles.

:13:47 A. I am not aware of any patent. Again, as I mentioned  
:13:51 earlier in my testimony, that modular augmentation was in  
:13:56 revision components.

:13:58 So, again, I have not seen a patent that shows  
:14:02 the modular buildup on the posterior condyle.

:14:06 Q. You mean a product?

:14:07 A. A product. But again, that modular buildup is a  
:14:13 revision system in the LCCK prosthesis. So there is a  
:14:19 product that has that buildup on it. Again, that is for a  
:14:22 very much different reason. That is, again, as we talked  
:14:25 about earlier this morning, in revisions to deal with bone  
:14:28 loss and restore stability to the knee. That is different  
:14:31 than that particular patent on the four-compartment patent.

:14:37 Q. The modular feature you have described in the prior

Scuderi - cross

:14:40 art is different than the modular feature claimed in the  
:14:43 '786 patent. Is that fair?

:14:45 A. Yes.

:14:45 Q. And you are not aware of any Zimmer product that  
:14:48 practices the claims of the '786 patent. Correct?

:14:53 A. The claims of the '786 patent, it's the four  
:14:57 compartment --

:14:58 Q. With the modular --

:15:00 A. With a modular augmentation, I am unaware of any.

:15:04 Q. You are unaware?

:15:05 A. Yes, I am unaware. I haven't found any in my  
:15:10 investigation. If you have one, let me know.

:15:12 Q. You were deposed in this proceeding. Correct?

:15:29 A. Yes.

:15:30 Q. One of the things that you did before your deposition  
:15:33 in this case was review the deposition that Dr. Scott had  
:15:37 given. Correct?

:15:43 A. I sat for part of Dr. Scott's deposition.

:15:45 Q. You were there for part of Dr. Scott's deposition?

:15:48 A. Yes.

:15:48 Q. And when you watched Dr. Scott's deposition, one of  
:15:54 the things that you heard Dr. Scott say was that it would be  
:15:58 impossible to determine which of the four of you, and that's  
:16:02 a reference to Dr. Insall, Dr. Kelly, Dr. Scott and  
:16:06 yourself, had any particular idea first during these

Scuderi - cross

discussions. Is that correct?

A. Yes.

Q. And you agree with that statement by Dr. Scott.

Correct?

A. Yes. It was very much a collaborative process and we were always conversing back and forth about these ideas.

Q. So you are not able today to offer any claim that you had an idea first. Correct?

A. You know, again, as I said, this was very much a collaborative process. We sat together, discussing design features and design ideas. It was very much a collaborative process. It is difficult to say who said what first.

Q. All right. You can't identify any specific contributions, I take it, that Dr. Scott made first in the discussions?

A. You know, similar to what I said before, in part of the collaborative process, each and every one of us made design suggestions, ideas and concepts. It was all brought forth throughout our dialogue. At times there may have been comments made by Dr. Scott first, by myself first, Dr. Insall first. And we would go back and forth until we at least thought we had an idea that we could move forward with, again, through that iterative process, go back and forth.

Q. You believe that Dr. Kelly should also be a named

Scuderi - cross

inventor on the patents. Correct?

A. Yes. I believe Dr. Kelly did contribute to the project.

Q. And so you believe that he should be a named inventor as well. Correct?

A. I think, as I said, Dr. Kelly was a part of the development team. He did make contributions to the product, just as I have stated before.

Q. Your answer is, yes, he should also be an inventor?

A. You know, I think he definitely made contributions to this and should seriously be considered as part of the design and development team.

Q. Let me have you take a look at your deposition again. I am going to direct you to Page 64. Lines 4 through 9. Let me know when you have had a chance to read that?

A. Yes, I have read it.

Q. The question that was asked of you is, "Well, I'm asking about what your belief is. Do you believe that Dr. Kelly should be named as an inventor on the patents at issue in this case?"

Your answer was: "Yes."

Do you see that?

A. Yes.

Q. That was truthfully given at the time?

A. Yes.

Scuderi - cross

Q. During your direct examination testimony you described a meeting in Dr. Insall's office, sitting around his table, that you say was in April of 1995. Do you recall that?

A. Yes.

Q. And if I understood correctly, your testimony is that it's at that meeting where this thickening of the posterior condyles and high flexion concept was first discussed among the doctors?

A. Yes.

Q. And when I say the doctors, I mean the four of you at ISK, Dr. Insall, Dr. Scott, Dr. Kelly and yourself?

A. Yes.

Q. That meeting occurred, if I heard you correctly, after Dr. Insall had returned from a trip to Japan?

A. Somewhere around that time when he had been in Japan.

Q. I think you said after he got back from Japan you had this discussion in his office?

A. Yes.

Q. Now, you don't have any records that demonstrate when this meeting occurred. Correct?

A. We have no written or formal records.

Q. You didn't take any notes at the meeting. Correct?

A. We did have some drawings and renderings as we were sketching it out. But nothing was saved. We could not find anything. Nothing was saved.

Scuderi - cross

:20:06 Q. The only people at the meeting, as you have described  
:20:08 it, were the four doctors. Correct?

:20:10 A. Correct.

:20:11 Q. Now, there is no evidence in the documentary record we  
:20:17 have of exactly on which date this meeting is alleged to  
:20:20 have occurred. Correct?

:20:22 A. Correct.

:20:22 Q. A number of people have talked, including yourself,  
:20:57 Dr. Scuderi, about Dr. Insall. You have heard this  
:21:00 testimony and given some yourself. Correct?

:21:02 A. Yes.

:21:02 Q. And consistently, people have noted him, as did you,  
:21:08 as the godfather of the knee, various iterations. Correct?  
:21:14 All sentiments that you agree with?

:21:15 A. Yes.

:21:16 Q. Now, you don't believe that Dr. Insall would take  
:21:24 credit for work that he believed was yours. Is that fair?

:21:30 A. That would be fair.

:21:30 Q. Or work that he believed you were involved in?

:21:37 A. That would be fair. He would not take my work and  
:21:41 make claim to it.

:21:42 Q. I take it you would agree with that also as to Dr.  
:21:44 Scott, you don't think Dr. Insall would wrongfully take  
:21:49 credit for the work of Dr. Scott or Dr. Kelly?

:21:53 A. Truly, Dr. Insall was a fair and honest man.



Scuderi - cross

Q. Now, you believe that Dr. Insall was aware of all of the contributions that you contend you made to the patents at issue, you would agree with that. Correct?

A. Yes.

Q. You are not aware of Dr. Insall telling anyone that you should also be named on the patents at issue. Correct?

A. Correct.

Q. And, as I understand, you claim that Dr. Insall didn't tell you, or to your knowledge Dr. Scott, about the patents or the fact that they were being applied for or that he had even sent anything to Zimmer about them?

A. Yes. I was very surprised that we had not been named on the patents myself. Dr. Scott, if we had known about that and if Dr. Insall had been alive when the patents were issued, or was in good health and we were aware of those patents, we would have definitely had a discussion with him about that issue and probably come to a sooner resolution.

Q. You never told Zimmer about any belief that you had that these ideas that you claim you were involved in were patentable?

A. You know, again, in part of the process that we designed and with the implant, I had no discussions with Zimmer that these were, you know, patentable ideas. We worked hard on the project to complete it, and again, in a collaborative way, with Dr. Insall as our primary

Scuderi - cross

:23:28 spokesperson and leader, conveyed that information to  
:23:31 Zimmer.

:23:31 Q. And so the answer to my question is you never told  
:23:35 anyone at Zimmer that you thought there were ideas out there  
:23:38 about high flexion or mobile-bearing knee that you had  
:23:42 contributed to and that might be patentable, we should think  
:23:44 about this?

:23:45 A. You know, I worked very hard on that project to  
:23:48 complete it and to develop a very successful product as part  
:23:54 of a team. That information was passed to the engineers  
:23:59 through our collaborative process, through that iterative  
:24:02 process, in the meetings, in the cad studies, in the  
:24:06 surgery. If there were patentable ideas that came through  
:24:10 it, I would have relied upon those individuals who were on  
:24:13 the team to work with us. Also, to bring that to our  
:24:16 attention. And, two, I was unaware that the patents had  
:24:19 actually been filed. If I had known that they had been  
:24:21 filed, I would have addressed it back in 1998.

:24:29 Q. So as you have described Dr. Insall in this context as  
:24:33 the leader of this effort, you were relying on Dr. Insall to  
:24:39 deal with such an issue, or you didn't even think about it,  
:24:43 perhaps?

:24:43 A. I really didn't think about it. I just continued to  
:24:46 work on the project with Dr. Insall and Dr. Scott. We  
:24:48 wanted to accomplish what our mission was. Our mission was

Scuderi - cross

:24:51 to design a very successful product. We gave a lot of  
:24:55 information, a lot of intellectual property, you know,  
:24:58 through the process, to the Zimmer engineers and many of  
:25:01 them are listed on the patent, also. Bill Roy says we were  
:25:07 the design surgeons involved on that project, as the  
:25:10 documents also state.

:25:14 Q. There have been occasions, or at least one occasion,  
:25:16 have there not, Dr. Scuderi, where did you did approach  
:25:19 Zimmer about something that you thought was patentable?

:25:21 A. That's correct.

:25:21 Q. And, in fact, there was an occasion where you had  
:25:25 conversations with Dr. Insall about the patentability of  
:25:28 some idea that you had come up with and Dr. Insall suggested  
:25:31 that you reach out to Zimmer and work with them on that.

:25:34 Correct?

:25:35 A. Yes.

:25:35 Q. So you knew that dialogue was available to you?

:25:39 A. That dialogue was always available when you have an  
:25:41 idea that you think is patentable. That was actually a  
:25:45 research project that we had done, looking at the distal  
:25:48 femur and developing an instrument system, that was going on  
:25:55 concomitantly as we were redesigning LPS, we were looking at  
:25:58 the High-Flex. And Dr. Insall made a recommendation that we  
:26:02 pass that information off to Zimmer to see if we could  
:26:06 actually patent that instrument.

Scuderi - cross

:26:32 MR. HALES: Your Honor, I would like to use a  
:26:34 demonstrative board that is one I understand Mr. Friedman  
:26:37 has objected to, or his side has objected to.

:26:42 They are okay.

:26:44 BY MR. HALES:

:26:45 Q. Can you see that okay, Dr. Scuderi?

:27:13 A. Yes.

:27:14 Q. Now, this is Defendants' Trial Exhibit 110, the way  
:27:25 it's been used.

:27:27 MR. HALES: If I can approach and examine from  
:27:28 the board for a moment, Your Honor?

:27:30 THE COURT: You may, counsel.

:27:31 BY MR. HALES:

:27:32 Q. You have seen this document before, Dr. Scuderi?

:27:36 A. Yes.

:27:36 Q. Now, the actual document is one that you hadn't seen  
:27:41 until litigation. Correct?

:27:44 A. That is correct.

:27:45 Q. Now, you recognize it from your reviewing the  
:27:50 litigation, it's a fax that was sent from Dr. Insall to  
:27:56 Audrey Beckman on May 1st, 1995. Correct?

:27:59 A. Yes.

:27:59 Q. And Audrey, Dear Audrey is Ms. Beckman?

:28:03 A. Yes.

:28:03 Q. You recognize J.I. as John Insall?

Scuderi - cross

:28:06 A. Yes.

:28:06 Q. And on it is depicted, and you have testified about  
:28:12 this from the beginning, a femoral component. Correct?

:28:15 A. Yes.

:28:15 Q. And it shows a buildup or thickening of the posterior  
:28:18 condyle. Correct?

:28:19 A. Yes.

:28:20 Q. And in it, Dr. Insall indicates that, I believe that  
:28:26 taken with the NexGen cam and post interaction that this  
:28:31 could be patentable as a full flexion knee for the Asian  
:28:35 countries.

:28:35 Do you see that?

:28:36 A. I see that, right.

:28:37 Q. You can read Dr. Insall's handwriting?

:28:40 A. I can read it.

:28:41 Q. So I managed to get it right, I think.

:28:44 A. Yes.

:28:44 Q. Now, as I think I just clarified, you had never seen  
:28:49 this until this dispute was under way?

:28:53 A. I never saw the document. I have seen the drawing. I  
:28:55 mean, we had that, something similar that we had sketched  
:28:58 out with Dr. Insall. So I did not see that document.

:29:02 Q. Now, Defendants' Trial Exhibit 110, this is a diagram  
:29:08 depicting the High-Flex knee that eventually became released  
:29:15 as LPS Flex, or the concept of it?

Scuderi - cross

A. That is not the exact design. LPS Flex. It is an idea that went through many other iterations till we got to the actual implant.

Q. Now, neither you nor Dr. Scott are indicated anywhere on here as having been involved in the creation of the document or receiving the document. Correct?

A. We didn't create the document nor did we receive the document. Again, that was very similar to a drawing that we had previously sketched. Again, similar to some other experience that we had with the five-millimeter augmentation on the back of the femoral component.

As I testified earlier, five millimeters was the size of the modular augment, and again, it was a matter of trying to build up that posterior condyle. Again, it is just showing thickening of the posterior condyle.

He does mention the NexGen cam and post mechanism. That is not drawn on the picture. He talks about full flexion. There is nothing there that shows that it's definitely a full flexion knee that's going to need a lot of work. It's basically a stick figure that starts everything.

Q. All right. Now, you mentioned a couple of times the prior drawing that you had seen like this. Not the one in this document but a different sketch?

A. Yes.

Scuderi - cross

Q. Now, that's a drawing that you saw Dr. Insall make.

Correct?

A. No. The prior drawings were, again, as we sat in a very collaborative way, if I had a sketch pad, sitting around the desk, I am drawing figures. I am saying, John, why don't we think about the modular augment, I testified to that earlier. What if we don't go modular? What if we actually flex the component?

We looked at some of our x-rays in prior studies and we found we had flexure of the terminal component. You can actually put that posterior condyle in, not have to resect this bone, and build up the posterior condyle, that flexing component. We talked about all of those issues prior. That was contemporaneous.

Q. Isn't it a fact that the first time you saw a sketch like this was when Dr. Insall first sketched it, which you say was prior to the May 1, '95 date?

A. No. I am going to say, again, we sketched this out. We actually have -- when we are sitting around the table, we have implants sitting on the table, again because of the fact that, you know, we are so interested in the knee. We had revision pieces. We usually just picked up a five-millimeter augment. Why is that five to six millimeters? That is what we had with the five-millimeter augment in our vision test. That is what we thought about

Scuderi - cross

:31:56 constantly adding, the five-millimeter augment, actually, we  
:31:59 got into it, it's too thick, it's too much bone to take out  
:32:02 on a primary knee.

:32:05 Q. Let me have you turn to your deposition again. I am  
:32:09 going to direct your attention to 228, Lines 2 through 13.  
:32:31 Let me know when you have had a chance to read that?

:32:51 A. Okay.

:32:53 Q. So the question asked you there is "And then you also  
:32:57 mentioned that you contend that you saw this drawing when  
:32:59 John first sketched it -- and I think you mean John Insall  
:33:03 -- "prior to May 1, 1995?"

:33:06 MR. FRIEDMAN: Can you read the rest of it?

:33:08 MR. HALES: I am not done yet.

:33:10 BY MR. HALES:

:33:12 Q. "When do you recall seeing John Insall sketch this  
:33:16 prior to May 1, 1995?

:33:18 "Answer: I think I testified earlier today that  
:33:20 John returned from Japan in April of 1995 and he brought to  
:33:23 our attention the need for a high flexion implant, and I  
:33:27 believe I have testified earlier today as to what centered  
:33:31 around that discussion."

:33:33 Have I stated that accurately?

:33:34 A. Yes.

:33:36 Then Line 17, it was part of our meeting again,  
:33:39 it was a more formal meeting with Dr. Insall and myself, Dr.



Scuderi - cross

:33:42 Scott, in which we discussed the option of trying to create  
:33:45 some augmentation of the posterior condyle to build up a  
:33:48 High-Flex type of implant.

:33:53 Do you know what happened -- you can redirect.

:34:09 Q. Let me take a look at -- or have you take a look at  
:34:28 PTX-191?

:34:49 A. I see it.

:34:49 Q. You testified about this document on your direct  
:34:52 examination?

:34:52 A. Yes.

:34:53 Q. These are notes that you recorded around August 4th of  
:34:59 1998. Correct?

:35:01 A. Yes.

:35:01 Q. So sometimes, apparently, folks at ISK kept notes.  
:35:07 Correct?

:35:07 A. Well, this was one occasion where I was offsite, I  
:35:15 believe I was home making some notations after we had  
:35:19 identified the problems I mentioned earlier about the  
:35:21 anterior liftoff, coming up with solutions. So I jotted  
:35:24 down some notes to help me when I got back to the office the  
:35:27 following day to discuss this with the group, Dr. Scott and  
:35:31 Dr. Insall.

:35:31 Q. Now -- and I am going to take this board down, because  
:35:44 we don't need to block counsel.

:35:46 Okay. Dr. Scuderi, the title on this document

Scuderi - cross

is High-Flex Fixed-Bearing Tibial Tray.

Correct?

A. Yes.

Q. This is all in your handwriting I take it?

A. Yes.

Q. Now, you are contending that this document supports your contributions regarding the '283 patent. Correct?

A. Yes.

Q. Now, the '283 patent claims, I think you will agree, relate to a mobile-bearing knee. Correct?

A. That's correct.

Q. The other page of this document, the third page, that has figures on it that you talked about during your direct examination, also says at the top, High-Flex fixed-bearing tibial tray. Correct?

A. That's correct.

Q. And you would agree that this document relates to the method of attachment between poly and tib tray in High-Flex fix. Correct?

A. Yes.

Q. What you have identified is the idea of adding a screw. Correct?

A. Correct.

Q. Now, the screw you are talking about is a screw similar to what Zimmer was using in its NexGen LCCK product.

Scuderi - cross

Correct?

A. For a much different reason. It's completely different, though. The utility of that screw.

Q. But the screw is similar to the one Zimmer was already using there?

A. It is a screw that comes into a different type of housing. Zimmer did not have the Morris tapered plug that was identified on that particular drawing. That did not exist at the time that was being drawn.

Q. If we go back to Page 1, Item 1, what you are writing says is, keep original NexGen locking mechanism but add a screw similar to LCCK. Correct?

A. Correct. I mean, it was similar with the idea to lock down that polyethylene. I would agree. But again, for the LCCK, it was to keep the polyethylene locked into place for Valgus stresses that came across the interface. In this particular case we were dealing with the anterior liftoff, the rocking movement and we wanted to lock that down.

Again, as I mentioned in my earlier testimony, the central stem was hollow and we had no way of fixing it unless we came up with some type of locking mechanism.

So the screw is a similar screw to the LCCK, yes. The utility is different. We had to create a new locking mechanism. And that became the taper plug, which the illustration shows as a washer or Morris taper plug.

Scuderi - cross

Q. The screw in the LCCK is used to help lock the poly down the tibial plate. Correct?

A. Correct.

Q. The LCCK, if I understand correctly, that product was released by Zimmer in approximately 1997. Is that correct?

A. That's correct. That was on the -- I was a consultant on that project, also.

Q. Now, the ideas that are in PTX-191 came first from you. Correct?

A. Well, as I mentioned earlier, it is an idea that I sketched, you know, offsite, I could bring it back to the office the following day and then collaborate with Dr. Insall and Dr. Scott to, can we optimize this, what direction do we need to go? Well, this actually solved the problem that was identified to us. And remember, Zimmer had come to the engineers had come to us with the liftoff problem, and we had to solve it with both the fixed-bearing as well as the mobile-bearing knee. We ultimately figured it out with the screw mechanism. And in similar fashion, on the mobile, it was a lot easier because we can put the screw right into the trunnion, the stem was of a more solid configuration, and we could not go right through the poly and lock it into the base plate. That would disrupt the entire mechanism.

Q. My question was, I think, a lot simpler than that. It

Scuderi - cross

was the initial ideas in PTX-191 you contend came from you.

Correct?

A. That's my drawing that I passed off to the team, yes.

And I testified to that. And I would say yes.

Q. And then after coming up with the idea, you went back and engaged in your collaborative process. Correct?

A. Yes.

Q. Now, the ideas in this document, PTX-191, did not come from Dr. Scott. Correct?

A. It initiated with my drawing and then in collaboration with Dr. Scott and Dr. Insall we came up with a design solution.

Q. Dr. Scott didn't have involvement in the initial ideas that you wrote yourself in PTX-191. Correct?

A. Again, that's my drawing. I initiated that idea.

Q. Now, we have already had a little bit of discussion at the beginning about documents at ISK and so forth. I want to ask a few more questions on that subject.

You shared staff with Dr. Insall while he was alive. Correct?

A. Yes.

Q. Secretary, reception, physician's assistants?

A. Yes.

Q. You and Dr. Insall shared those?

A. Yes.

Scuderi - cross

Q. Does the explanation that you gave today resolve uncertainty you had before about what happened to Dr. Insall's files in your mind as files that related to Zimmer's prostheses?

A. It does.

Q. Now, you possessed correspondence between Dr. Insall and Zimmer on which you were not copied before this case began. Correct?

A. Yes.

Q. And before Dr. Insall died, he gave you copies of correspondence between himself and Zimmer on which you were not copied from time to time. Correct?

A. Yes.

Q. The documents that you had under your desk for a while, did that contain correspondence between Zimmer and Dr. Insall?

A. Between myself and Dr. Insall?

Q. No. Between Zimmer and Dr. Insall.

A. Yes.

Q. Let me have you take a look at DTX-261. Do you see DTX-261?

A. Yes.

Q. DTX-261 was produced by you and Dr. Scott in this action. Correct?

A. Yes.

Scuderi - cross

Q. It's got the S&S Bates stamp at the bottom that indicates that?

A. Yes, it does.

Q. Now, you claim the first time you saw this document was during the case?

A. That's correct.

Q. Do you know how this document ended up in your production?

A. Again, going back to my earlier testimony about the boxes that were given to me in 2006, that's where that document came from, and those files, which I had not looked at until 2009.

Q. Now, in this document, DTX-261, there is information -- sorry. This is a document from Cary Reeves at Zimmer, who is patent counsel at Zimmer, to Dr. Insall. Correct?

A. Yes.

Q. And in the first line he talks about informing, he is writing to inform you, which is Dr. Insall, of the status of my patent-related activities regarding high-flexion knees. Correct?

A. I see that, yes.

Q. So let me take a look at DTX-72, or have you take a look at it.

A. I see that.

Scuderi - cross

Q. This is another document produced by you and Dr. Scott in this case. Correct?

A. It has SS numbers on the bottom.

Q. And it's a document that goes from, again, counsel for Zimmer to somebody named John Irwin. Do you know who John Irwin is?

A. I just know he was John's attorney.

Q. He was Dr. Insall's attorney?

A. Dr. Insall's attorney, yes.

Q. This is correspondence from Zimmer's counsel to Dr. Insall's counsel?

A. Yes.

Q. And in the bullet points on the lower part of the the first page you see an identification of the '729 patent there?

A. I do.

Q. Below that there is an identification of Serial No. 346850?

A. Yes.

Q. That relates to a mobile tibial tray implant. Do you see that?

A. Yes.

Q. Do you understand that to be a reference to the application that led to the '283 patent?

A. Yes.



Scuderi - cross

:46:11 Q. Now, this, I think, is the document or one of them  
:46:20 that you initially claimed most likely came from Dr. Scott's  
:46:23 files. Is that right?

:46:25 A. That's correct. Because if you look at the date, it's  
:46:28 June 8th, 2001. John had passed December 2000. All his  
:46:35 mail and correspondence was put in an envelope and picked up  
:46:39 by his wife. I would not have gotten any mail or  
:46:42 correspondence that was addressed to John Insall in my  
:46:46 possession or in my office.

:46:47 So again, placed into a box, envelope, picked up  
:46:51 by Mrs. Insall on a weekly basis.

:46:54 Again, this is after John's passing.

:46:56 Q. Right. But Mrs. Insall didn't take this document with  
:47:00 her apparently. Correct?

:47:02 A. You know what? I will be honest with you -- I am  
:47:05 definitely being -- I am under oath so I am honest.

:47:08 MR. HALES: That's the first moment, Your Honor.

:47:12 THE WITNESS: It's not the first moment. I have  
:47:15 been honest the whole time.

:47:17 Again, upon John's passing, in December, his  
:47:20 mail was not opened by us, we had nothing to do with John.  
:47:24 That was put into a box, packaged to Mrs. Insall. What  
:47:31 happened after that I don't know.

:47:32 BY MR. HALES:

:47:32 Q. It certainly came back to your files. Correct?

Scuderi - cross

A. And I see that. But again, it didn't come out of my box.

Q. Is this out of the files that were under your desk?

A. Again, it would not be if it was a 2001. Again, upon, you know, when we shut John's office, Mary Insall came by within a month or two and we gave her all -- she selected all his files and personal belongings, packaged it up. Everything else got boxed. Again, all mail that came in after John's passing went into an envelope. Once a week, Mary Insall lived across the street, she or one of her, you know, delegates picked it up and it went.

So I did not have possession of this one.

Q. So DTX-72 is a document that did not come out of the boxes that were in your garage and basement?

A. Correct.

Q. So I take it that your claim at your deposition that it most likely came from Dr. Scott's files you would still hold?

A. Yes.

Q. Let's take a look at DTX-275. DTX-275 is another letter from Mr. -- it's a letter from Mr. Schoenle, Zimmer patent counsel, to Dr. Insall?

A. I do not have DTX-75.

Q. 275.

A. 275.

Scuderi - cross

:49:35 Q. Let me know when you get there?

:49:38 A. Okay.

:49:38 Q. This is a January 26th, 2000 letter from Mr. Schoenle  
:49:43 to Dr. Insall. Do you see that?

:49:44 A. Yes.

:49:44 Q. Another document produced by you and Dr. Scott in the  
:49:47 case?

:49:48 A. Yes. It's an SS number on the bottom.

:49:50 Q. So this address there, ten Gracie Square, what is  
:49:55 that, is that Dr. Insall's --

:49:58 A. That is Dr. Insall's private residence across the  
:50:00 street.

:50:00 Q. That is his home address?

:50:02 A. Home.

:50:08 Q. Let's take a look at Defendants' Trial Exhibit 73.

:50:55 A. I see it.

:50:56 Q. Okay. You recognize Defendants' Trial Exhibit 73, Dr.  
:51:01 Scuderi?

:51:02 A. Yes, I do.

:51:02 Q. This is a patent on which Dr. Insall and you are named  
:51:10 inventors. Correct?

:51:11 A. Yes.

:51:11 Q. And this was filed on October 30th, 1996 and issued  
:51:17 November 3rd, 1998. Correct?

:51:20 A. Yes.

Scuderi - cross

Q. Around the time that you were working on LPS and LPS Flex, so forth?

A. Yes. Multiple projects were ongoing at that time.

Q. Dr. Scott is not a named inventor on the '216 patent. Correct?

A. That's correct.

Q. And you don't have any reason to believe that Dr. Scott should be a named inventor on the '216 patent. Correct?

A. Correct.

Q. This is something that you and Dr. Insall did with the Zimmer engineers that were named without Dr. Scott?

A. Yes, it was a research project that I had done with Pascale Pollvach (phonetic). He was one of our visiting international fellows. It was work we had done. Out of that came the instrument system that you see here.

Q. Not everything that happens at ISK happens among all four doctors. Correct?

A. This was an instrument project that was very different than an implant design and development project. So this was a completely different project that was running with a research fellow and myself and Dr. Insall. So, a clinical publication, Clinical Orthopedics, this was even the basis of our morphologic measurements on the distal femur and Gender supported materials.

Scuderi - cross

:52:32                    Again, this was a side project that we were  
:52:35                    doing, not on implant design but on instrumentation and  
:52:38                    technique.

:52:38                    Q.        The answer to my question is, yes, not everything that  
:52:41                    happens at ISK has all of the four doctors involved?

:52:45                    A.        Correct. As you see here, it was Dr. Insall and  
:52:48                    myself.

:52:48                    Q.        Take a look, if you would, at Defendants' Trial  
:52:51                    Exhibit 74.

:53:06                    A.        I see it.

:53:06                    Q.        So, now, is this document, Trial Exhibit 74, related  
:53:16                    to trial Exhibit 73, the '216 patent?

:53:20                    A.        Yes, it is.

:53:20                    Q.        And so it's actually an effort to improve the NexGen  
:53:25                    knee instrument system. Correct?

:53:27                    A.        That is correct.

:53:28                    Q.        Product?

:53:28                    A.        Yes.

:53:29                    Q.        Now, what it indicates here is that you and Dr. Insall  
:53:34                    designed this instrument, I think you testified similar to  
:53:37                    that. Correct?

:53:38                    A.        Yes.

:53:38                    Q.        Now, as I recall -- I believe Dr. Insall suggested  
:53:45                    that you send this letter to Zimmer. Correct?

:53:47                    A.        Yes.

Scuderi - cross

:53:48 Q. I take it that with respect to LPS Flex, I know you  
:54:09 didn't have any conversations with Dr. Insall or Zimmer  
:54:14 about whether ideas on LPS Flex should be patented.  
:54:18 Correct?

:54:18 A. Correct.

:54:18 Q. And I take it you never at any point followed up and  
:54:22 said, hey, you know, all this work we have done, we should  
:54:25 file a patent application on these or pursue that?

:54:29 A. We were so consumed in the design of the implant that  
:54:31 we got involved in everything, and it really just never came  
:54:34 up for discussion amongst any of us.

:54:39 Q. But here on August 21st, 1995, which is about the same  
:54:43 time in DTX-74, you are approaching Zimmer to pursue, or  
:54:47 suggest patent protection on an instrument for the NexGen  
:54:51 knee?

:54:51 A. Yes. So in this particular one, it was again, as I  
:54:54 mentioned earlier, a project that we had been working on for  
:54:58 the NexGen system. Everything was for the NexGen system at  
:55:01 that time. Both implants as well as instruments.

:55:03 What is interesting, I never actually saw the  
:55:06 patent until 2009, when I investigated the LPS patents. It  
:55:14 was never brought to my attention that Zimmer had actually  
:55:17 gotten the patent.

:55:17 Q. Well, I have a few more questions for you. I am  
:55:22 almost done.

Scuderi - cross

:55:23 LPS Flex fixed, the team who actually design the  
:55:29 LPS Flex fixed prosthesis was formed in 2007. Is that  
:55:33 correct?

:55:33 A. Yes -- no, not 2007.

:55:38 Q. 1997.

:55:39 A. Okay.

:55:39 Q. 1997. Correct?

:55:47 A. Yes.

:55:47 Q. Not everybody who worked on the LPS Flex project is a  
:55:53 named inventor on the patents at issue. Correct?

:55:56 A. That is correct.

:55:56 Q. And I think you would agree that not everybody who --  
:56:00 not everybody who worked on the LPS Flex product should be a  
:56:04 named inventor on patents at issue?

:56:07 A. Correct.

:56:07 Q. You have been implanting LPS Flex fixed for a majority  
:56:12 of your surgeries since 1999. Is that right?

:56:18 A. That's correct. That was part of the IB study. I was  
:56:21 the principal investigator for the IB.

:56:23 Q. You have implanted more than a thousand of them?

:56:25 A. Yes.

:56:27 Q. LPS Flex mobile, the team for LPS Flex mobile to  
:56:30 develop the prosthesis, was that formed in 1997?

:56:34 A. Yes.

:56:34 Q. Not everybody who worked on LPS Flex mobile is or

Scuderi - cross

:56:38 should be a named inventor on the patents at issue. Is that  
:56:41 fair?

:56:41 A. Correct.

:56:41 Q. You have been implanting LPS Flex mobile since about  
:56:46 1999 or 2000?

:56:48 A. We had that hiatus because of the fact that we had  
:56:51 regulatory issues and it wasn't until about 2005, 2006, I  
:56:56 can't recall the exact date where we got the FDA release for  
:56:59 the United States. Remember, it was a Class 3 product. So  
:57:02 we couldn't do it. We did the first one in 1999. Because  
:57:07 of the IDE study, we had to stop immediately after the  
completion.

:57:13 Q. I think you have implanted a hundred or more?

:57:15 A. A few hundred.

:57:16 Q. Now, you were implanting LPS, NexGen LPS by 1996 or  
:57:24 thereabouts. Correct?

:57:25 A. I believe I put one of the first ones in, I think it  
:57:28 was August of '96.

:57:29 Q. So LPS was on the market and being used by August of  
:57:32 1996?

:57:33 A. Yes.

:57:33 Q. And I think we already asked, just to be clear, LCCK,  
:57:40 that was introduced in 1997. Correct?

:57:43 A. Yes. I did one of the first ones right around that  
:57:47 time.



Scuderi - cross

:57:51 MR. HALES: I have got no further questions,  
:57:53 Your Honor.

:57:53 THE COURT: Let's have redirect after a break.

:57:59 (Recess taken.)

:58:01 THE COURT: Please take your seats. Please  
:19:35 continue.

:19:36 REDIRECT EXAMINATION

:19:38 BY MR. FRIEDMAN:

:19:40 Q. Could you put up, please, DTX-136. I think I am  
:19:53 particularly interested in what was going to be the second  
:19:56 or third page of that exhibit. Maybe it's not DTX-136.

:20:03 Yes, there it is. Next page.

:20:07 If you could just -- this document is a document  
:20:16 that I think you said was received by you from Zimmer. Is  
:20:26 that correct?

:20:26 A. Yes.

:20:27 Q. And that was, were you being asked to review that  
:20:50 document as a draft?

:20:53 A. Yes.

:20:54 Q. Did you review that draft and make any comments or  
:21:00 changes to it and send it back?

:21:02 A. I made no changes to it.

:21:05 Q. Now, you note in the first full paragraph, it says,  
:21:13 "Our engineers and developing surgeons, Dr. Insall, Scuderi,  
:21:18 and Kelly have designed this product."

Scuderi - cross

:21:25                   Mr. Hales asked you a question about that. It  
:21:28 doesn't show Dr. Scott, does it?

:21:31 A.       It does not.

:21:31 Q.       And, in fact, it doesn't show anybody else except the  
:21:36 three of you, Insall, Scuderi and Kelly. Correct?

:21:40 A.       Correct.

:21:40 Q.       Now, if we could, let's take a look at the final  
:21:45 version of that, which is PTX-176. We will go to the same  
:21:56 paragraph. Enlarge it, please.

:22:04                   Now, you will note that this paragraph is  
:22:07 different, correct, from the paragraph that we just saw?

:22:12 A.       Yes.

:22:12 Q.       There are words that have been added. Correct?

:22:17 A.       Yes.

:22:17 Q.       Do you know how it is that those words were added in  
:22:22 the final version of this document?

:22:25 A.       I do not.

:22:26 Q.       When it says, "and others," do you know whether that  
:22:34 includes Dr. Scott?

:22:37                   MR. HALES: Objection. Leading. Foundation.

:22:42                   THE COURT: Can you establish a foundation for  
:22:45 this gentleman's knowledge?

:22:52                   MR. FRIEDMAN: No. I will move on.

:22:54 BY MR. FRIEDMAN:

:22:59 Q.       If we could go to, I think it was 203, I think it was

Scuderi - redirect

Defendants' 203. Now, you were asked a number of questions about this exhibit by Mr. Hales. Correct?

A. Yes.

Q. Is there any place in this exhibit where either Dr. Scott or Dr. Scuderi are mentioned?

A. There is no place that we are mentioned.

Q. Do you know from your recollection whether or not yourself and Dr. Scott attended the cadaver lab that's referred to in this document?

A. Yes. If that is a cadaver lab done at the ISK Institute, we were there.

Q. There is no place in these -- is there any place in these minutes where that is reflected?

A. There is no place anywhere in the minutes where anybody is listed.

Q. If we could put up PTX-338.

MR. HALES: I want to note for the record, I think Mr. Friedman called that DTX. It was PTX, for the record.

MR. FRIEDMAN: I am sorry.

BY MR. FRIEDMAN:

Q. Next page. Actually, I want the second page. That is fine, right there.

MR. HALES: I have an objection. This is beyond the scope of my cross-examination. I never used this

Scuderi - redirect

:24:47 document or explored it, although Mr. Friedman used it on  
:24:53 his direct.

:24:54 MR. FRIEDMAN: I think it's within the scope of  
:24:56 the cross, because on a number of occasions, Your Honor,  
:24:58 more than even this exhibit --

:25:00 THE COURT: This going to repeat something he  
:25:02 has already said? Are you just going to have him repeat  
:25:05 something that has already been said about this document? I  
:25:07 have heard it. I don't need to here it add nauseam.

:25:12 MR. FRIEDMAN: No.

:25:13 THE COURT: Let's take the document down and  
:25:16 move on.

:25:20 BY MR. FRIEDMAN:

:25:21 Q. Can we go, if we could, to what is probably DTX-189.  
:25:44 This also refers to a cadaver study. Correct?

:25:50 A. DTX-?

:25:52 Q. DTX -- I am sorry. PTX. PTX. I apologize to  
:26:02 everyone.

:26:10 A. I see it now.

:26:11 Q. Now, does this document indicate whether Dr. Scuderi,  
:26:21 yourself, was in attendance at this meeting?

:26:24 A. It does.

:26:24 Q. Now, can you recall whether, in fact, Dr. Scott was in  
:26:30 attendance at this meeting as well?

:26:33 A. Again, this is a cadaver lab at the ISK Institute on

Scuderi - redirect

June 25th and 26th. Dr. Scott was in attendance.

Q. By 1998, how many years had you been a developer surgeon for Zimmer?

A. At least four years.

Q. Do you know how long Dr. Scott had been a developer surgeon for Zimmer by 1998 or so?

MR. HALES: Your Honor, objection. Beyond the scope. I think Dr. Scott will testify in any event.

THE COURT: Let's move on. I am going to sustain the objection.

MR. FRIEDMAN: Okay.

THE COURT: I think you can move it along.

MR. FRIEDMAN: We will get to it differently.

BY MR. FRIEDMAN:

Q. At that point you had been a developer surgeon for roughly four years or so. Did anybody from Zimmer -- did you ever have discussions with anyone from Zimmer concerning whether you should be named as an inventor on any patents relating to the High-Flex?

A. No.

Q. Did you ever receive any of correspondence, phone calls, e-mails, from anyone at Zimmer, asking whether you had reason to believe that you should be named as an inventor?

A. No.

Scuderi - redirect

:28:11 MR. FRIEDMAN: Can I have one second, Your  
:28:13 Honor?

:28:14 THE COURT: Sure.

:28:16 MR. FRIEDMAN: There is nothing else I have to  
:28:19 do, Your Honor.

:28:19 THE COURT: Thank you, counsel. Doctor, you are  
:28:21 excused.

:28:22 (Witness excused.)

:28:51 MR. FRIEDMAN: At this juncture, Your Honor, I  
:28:53 think we are going to show a little bit of a deposition of  
:28:56 one of the witnesses, Mr. Davis.

:28:58 THE COURT: Okay.

:29:03 MR. FRIEDMAN: I am not quite sure who in IT is  
:29:07 doing this.

:29:14 "Question: And when you joined Zimmer in August  
:29:16 of 1987, what was your job title?

:29:20 "Answer: Supervisor, customer service."

:29:23 THE COURT: Who is this?

:29:26 MR. HALES: It's Todd Davis, Your Honor.

:29:28 THE COURT: Todd Davis.

:29:29 (Video played as follows.)

:29:29 "Question: And when you joined Zimmer in  
:29:35 August of 1987, what was your job title?

:29:39 "Answer: Supervisor, customer service.

:29:41 "Question: So in 1993 you assumed a new

Davis - depo.

:29:44 position?

:29:44 "Answer: I did, yes.

:29:45 "Question: And what was that?

:29:48 "Answer: Product manager in knees.

:29:50 "Question: And how long were you product  
:29:51 manager in knees?

:29:53 "Answer: I'm going to say 1997. I think it was  
:29:56 right around four years.

:29:58 "Question: And generally what did you do as  
:30:04 product manager in knees?

:30:08 "Answer: I first managed the product of the  
:30:11 Miller unit compartmental knees, and then went into the  
:30:16 Insall/Bustein knee product, and eventually ended up  
:30:24 managing the NexGen.

:30:28 "Question: So in 1997, what title did you  
:30:31 assume?

:30:32 "Answer: Director of U.S. knee marketing.

:30:34 "Question: How long, Mr. Davis, were you the  
:30:36 director of U.S. knee marketing?

:30:44 "Answer: I think again about four years. I  
:30:47 think until about 2001.

:30:49 "Question: And where are you employed now?

:30:55 "Answer: Biomet.

:30:58 "Question: And did you receive a degree?

:31:00 "Answer: I did.

Davis - depo.

:31:00 "Question: When and from where?

:31:05 "Answer: 1987 from Franklin University.

:31:08 "Question: In what?

:31:10 "Answer: Management science.

:31:11 "Question: Any other college or university  
:31:14 degrees?

:31:15 "Answer: No.

:31:15 "Question: What did you learn about how knee  
:31:18 devices are developed generally?

:31:20 "Answer: Well, a key component was  
:31:22 collaboration with orthopedic surgeons. You would build a  
:31:27 team to represent the markets in which they perform surgery,  
:31:31 and, you know, obviously driven by needs within the company  
:31:35 to develop a certain type of device.

:31:44 "Question: Now, when you're talking about knee  
:31:47 implant devices, without names specifically, but by general  
:31:51 description, what are the members of the team that Zimmer  
:31:54 would put together to develop a knee device?

:32:02 "Answer: That would start with development  
:32:04 engineers employed by the company, marketing representation,  
:32:07 which was myself or somebody from my team, and then  
:32:13 orthopedic surgeons.

:32:13 "Question: And if we're talking about knee  
:32:17 devices, generally speaking, what would that collaborative  
:32:20 effort consist of, how would it work?



Davis - depo.

:32:30 "Answer: Again, it would be much face-to-face  
:32:33 meeting time. There would be -- the project moves further  
:32:37 downstream and you would have product samples that would be  
:32:41 representative of what end product we believe would be  
:32:45 appropriate, then you would spend time in surgery with those  
:32:49 physicians that were part of the development team. They may  
:32:53 try the instrument in surgery. They may try to fit the  
:32:57 implant during a surgical procedure. Again, any number of  
:33:01 ways to collaborate.

:33:03 "Question: Now, would it also include at times  
:33:11 cadaver studies?

:33:12 "Answer: Yes.

:33:12 "Question: And what would follow the time that  
:33:15 was spent in surgery?

:33:17 "Answer: There would typically be a debrief.  
:33:20 Once the surgery was over, once physicians were out of the  
:33:24 OR, we would typically meet after the case or cases and  
:33:27 discuss with them their opinion of its performance.

:33:30 "Question: Would it happen from time to time in  
:33:35 this process that you've described that the surgeons would  
:33:43 make suggestions or recommendations about how to produce or  
:33:51 configure the product?

:33:57 "Answer: Yes.

:33:57 "Question: And generally, is this the process  
:34:03 that was followed when ISK was the group of outside surgeons

Davis - depo.

who were consulting on the development of products?

"Answer: Yes.

"Question: How frequently would you actually go to ISK during this period?

"Answer: I don't recall specifically.

Frequently, maybe once a quarter.

"Question: Once a quarter, during the entire period we talked about?

"Answer: Certainly in the '94 through '01 period, yes.

"Question: Okay. And so would you consider your attendance at cadaver studies and your attendance in surgeries to be part of the product development?

"Answer: Not in all cases, no.

"Question: And to the -- how many cadaver studies did you attend?

"Answer: I remember two specifically --

"Question: Were Dr. Scott and Dr. Scuderi at those cadaver studies at least for part of the time?

"Answer: As I recall, yes.

"Question: How many surgeries did you attend, best estimate?

"Answer: 50.

"Question: 50?

"Answer: Yeah.

Davis - depo.

:35:34 "Question: And those were surgeries that were  
:35:37 performed by ISK surgeons?

:35:41 "Answer: Yes.

:35:42 "Question: And who among the ISK surgeons  
:35:44 performed surgeries that you attended?

:35:47 "Answer: Dr. Insall, Dr. Scott, Dr. Scuderi,  
:35:50 Dr. Kelly, Doctor Cushner. I think those are the only five  
:35:54 that I observed in surgery.

:36:02 "Question: Was it your impression that they  
:36:08 were working together as a team?

:36:10 "Answer: Yes.

:36:14 "Question: And what is it that led you to the  
:36:16 conclusion that the three of them were working together as a  
:36:20 team?

:36:21 "Answer: Just my observations during my time in  
:36:23 New York to see them collaborate on surgical cases that they  
:36:27 had. Dr. Scuderi worked directly with Dr. Insall, so they  
:36:31 were in the same OR virtually every day. And Dr. Scott  
:36:35 operated in the OR right next to them. And, again, they  
:36:40 would compare cases at the end of the day, compare patients,  
:36:43 and generally behave as a group practice would.

:36:47 "Question: And were you ever present when the  
:36:49 doctors at ISK discussed knee devices that were being  
:36:53 developed?

:37:00 "Answer: Yes.

Davis - depo.

:37:10 "Question: And during these discussions, what  
:37:13 types of things were discussed?

:37:15 "Answer: I remember specifically in the '96,  
:37:19 '97 time frame when we were developing the High-Flex where  
:37:23 we would go in, do surgery with those samples that I  
:37:27 described previously. And then we'd meet in Dr. Insall's  
:37:31 office after the cases and describe, you know, how they  
:37:34 performed in the patients in which they were trialed, how  
:37:38 the instruments worked; and we did a lot of product  
:37:41 development in those meetings.

:37:46 "Question: For the High-Flex?

:37:49 "Answer: Yes.

:37:49 "Question: And were those meetings typically  
:38:05 attend by Dr. Insall, Dr. Scott, and Dr. Scuderi?

:38:11 "Answer: Yes.

:38:16 "Question: So as I understand it, if I'm trying  
:38:19 to visualize these meetings, the doctors who were there  
:38:24 based on their experiences and the surgeries that had just  
:38:27 taken place would make specific recommendations as to  
:38:32 changes that should be made on the device; is that how it  
:38:36 happened?

:38:37 "Answer: Yes.

:38:39 "Question: And do you recall whether specific  
:38:41 recommendations were made in these meetings at any time by  
:38:44 Dr. Scott?

Davis - depo.

:38:46 "Answer: I don't recall specifically.

:38:49 "Question: I show you what has been marked as  
:38:52 TD-2 for identification, Mr. Davis, which appears to be a  
:38:58 memo relating to minutes from an MBK development meeting  
:39:04 held in San Francisco.

:39:14 "And was Dr. Scott a member of the design team  
:39:18 for the MBK device?

:39:27 "Answer: He was, yes.

:39:29 "Question: Did Dr. Scott make contributions to  
:39:32 the development of the MBK device?

:39:36 "Answer: He did, yes.

:39:37 "Question: Okay. Do you know where Zimmer  
:39:43 first got the idea to produce a PS version of a  
:39:48 mobile-bearing knee?

:39:51 "Answer: I don't recall, no.

:39:52 "Question: Do you know whether it was Dr. Scott  
:39:54 who first suggested the possibility of there being a PS  
:39:59 version of a mobile-bearing knee?

:40:08 "Answer: I don't recall.

:40:12 "Question: I'd like to move on now to the  
:40:15 High-Flex knee program. Could you describe generally what  
:40:18 the High-Flex knee program consisted of?

:40:24 "Answer: It was an observation that Dr. Insall  
:40:28 had having spent some time in Japan and the lack of knee  
:40:32 replacement in Japan, he felt it was potentially the lack of

Davis - depo.

:40:36 flexion that current implants allow the patient to get. And  
:40:39 he thought that an implant that could achieve higher ranges  
:40:42 of flexion would help expand the Japanese market. So it was  
:40:50 taking the NexGen knee and create some mechanism, some  
:40:57 components that would promote higher flexion.

:41:01 "Question: In your view, did the High-Flex knee  
:41:05 program build upon NexGen?

:41:11 "Answer: Yes.

:41:12 "Question: Did it build also upon MBK?

:41:16 "Answer: It did not, no.

:41:17 "Question: What specific NexGen product or  
:41:20 products was the High-Flex built upon?

:41:24 "Answer: It was built upon the LPS, the Legacy  
:41:28 posterior stabilized system.

:41:30 "Question: When did you first become involved  
:41:31 in working with the High-Flex knee program?

:41:46 "Answer: I don't recall specifically, but it  
:41:51 would have been somewhere in the '97 time frame.

:41:59 "Question: And what was your involvement, Mr.  
:42:01 Davis, with the High-Flex knee program?

:42:07 "Answer: I don't recall specifically. I was  
:42:08 either the product manager or the director of the group that  
:42:12 was responsible for bringing it to market.

:42:15 "Question: From a marketing point of view?

:42:21 "Answer: Yes, correct.

Davis - depo.

:42:22 "Question: Did you -- do you recall whether you  
:42:26 attended any cadaver studies in conjunction with the  
:42:30 High-Flex?

:42:32 "Answer: Not specifically, no, I don't recall.

:42:33 "Question: And following each of the surgeries  
:42:36 that you attended, was there a post-surgical debriefing?

:42:45 "Answer: Yes.

:42:45 "Question: And once more, if you would, explain  
:42:59 what would take place at the post-surgical briefings --  
:43:02 debriefings following the High-Flex surgeries that you  
:43:05 attended.

:43:07 "Answer: Again, we would assemble in Dr.  
:43:09 Insall's office and then just review step by step the  
:43:12 surgical procedures that were followed, the function of the  
:43:16 implant, and offer suggestions for improvement or, yes, we  
:43:22 got it right and confirmation of the design that was at  
:43:28 place at that time.

:43:36 "Question: Without going to the specifics of  
:43:38 the suggestions, do you recall that Drs. Insall, Scuderi and  
:43:42 Scott did make suggestions as a result of these surgeries  
:43:45 during the post-surgical debriefing that were used for  
:43:49 product development?

:43:56 "Answer: Yes.

:43:59 "Question: And did each of them make such  
:44:01 contributions?

Davis - depo.

:44:05 "Answer: Yes.

:44:05 "Question: Do you remember any of the specific  
:44:08 contributions that Dr. Insall, Dr. Scuderi, or Dr. Scott  
:44:12 made?

:44:13 "Answer: I don't remember specifically who  
:44:14 contributed. I remember some of the design features that  
:44:17 came out of those meetings, but I don't recall if they came  
:44:23 from one or more of the doctors.

:44:26 "Question: Is it fair to say that ISK was  
:44:30 actually at the center of the Flex development?

:44:42 "Answer: Yes.

:44:44 "Question: What are the design features that  
:44:50 you remember that came out of the surgeries and the  
:44:53 post-surgical meetings that you just described?

:44:56 "Answer: Well, specifically on the articular  
:44:58 surface, we provided a deeper cut-out anteriorly. One of  
:45:07 the things that the engineers hadn't thought about was as  
:45:10 you achieve deeper flexion, where would the patella tendon  
:45:14 sit, and that was inhibiting deeper flexion. So we carved  
:45:18 out the anterior portion of the articular surface.

:45:21 "The cam-and-spine mechanism was altered from  
:45:25 the LPS as a result of what happened with that cam as it  
:45:29 went deeper into flexion. So it was elongated to allow for  
:45:35 better contact area in deep, deep flexion. And then just  
:45:39 generally the genesis for it was a thicker posterior



Davis - depo.

:45:44 condyle. So that was debated, how much bone could you  
:45:48 remove to achieve the higher degree of flexion.

:45:53 "And then on the instrument side, there was a  
:45:55 lot of discussion about how would we accomplish this, would  
:45:59 it be a unique femoral finishing guide, would you put in an  
:46:05 additional femoral guide on to finish these posterior  
:46:11 condyles, how would you clean up the posterior osteophytes;  
:46:16 and all of those were debated in large part in those  
:46:21 meetings in New York and other places.

:46:22 "Question: To the best of your recollection,  
:46:24 did Drs. Insall, Scuderi and Scott each contribute to these  
:46:30 four development features that came out of those meetings?

:46:36 "Answer: Yes.

:46:36 "Question: And would each of the surgeons make  
:46:41 specific contributions to the product development aspect of  
:46:46 these 4:00 afternoon meetings that you had?

:46:49 "Answer: Yes.

:46:53 "Question: Do you remember any of the specific  
:46:55 contributions that either Dr. Insall, Dr. Scott or Dr.  
:46:58 Scuderi made?

:46:59 "Answer: I do not, no.

:47:03 "Question: Do you have any specific  
:47:05 recollection of discussions with those three surgeons about  
:47:09 extended posterior condyles?

:47:12 "Answer: Yes.

Davis - depo.

:47:13 "Question: Were there multiple conversations  
:47:15 also with those three physicians concerning the spine/cam  
:47:22 mechanism?

:47:23 "Answer: Yes.

:47:23 "Question: And do you recall what any of the  
:47:25 doctors specifically said in any of those conversations  
:47:31 regarding the spine/cam mechanism?

:47:36 "Answer: No, I do not.

:47:38 "Question: And do you recall specifically what  
:47:40 any of the doctors said during any of those conversations  
:47:44 relating to the extended posterior condyles?

:47:48 "Answer: No.

:47:54 "Question: Did Zimmer rely upon the  
:47:56 recommendations of these three surgeons and incorporate  
:47:59 features into the products that were being developed?

:48:02 "Answer: Yes.

:48:05 "Question: Did Zimmer rely upon recommendations  
:48:08 of these three surgeons and incorporate features into the  
:48:12 actual design of products that were developed?

:48:15 "Answer: Yes.

:48:18 "Question: And one of those products would be  
:48:21 Flex?

:48:22 "Answer: The LPS Flex, yes.

:48:25 "Question: And then the answer to the last  
:48:28 question I asked, the three surgeons included Dr. Insall,

Davis - depo.

Dr. Scott, and Dr. Scuderi. Correct?

"Answer: Yes.

"Question: And as surgeons, did they provide the necessary design criteria to make the implants possible?

"Answer: They provided a great deal of the design input required, yes.

"Question: Do you recall whether you actually have read the patent from beginning to end at any time?

"Answer: I doubt that I read it from beginning to end. I would have focused on the claims.

"Question: -- for this. First is shaping the superior condyles to allow for flexion. That's the subject; that's the feature. Do you recall that you had conversations with Dr. Scott and Dr. Scuderi concerning the shaping of the superior condyles to allow for increased flexion?

"Answer: Yes.

"Question: Do you know on how many occasions?

"Answer: I don't. It would have been at least ten.

"Question: Do you recall with any specificity any of the conversations that you had with Dr. Scott and Dr. Scuderi concerning the shaping of the superior condyles to allow for increased flexion?

"Answer: No, I don't.

Davis - depo.

:50:12 "Question: Did each of them have some comment  
:50:14 or contribution to make regarding that feature?

:50:17 "Answer: I can't say with certainty. I know we  
:50:19 all discussed it.

:50:21 "Question: You do recall, though, that you all,  
:50:24 meaning yourself, Dr. Scott, and Dr. Scuderi, discussed that  
:50:29 feature, shaping the superior condyles to allow for  
:50:34 increased flexion. Is that correct?

:50:36 "Answer: Yes.

:50:37 "Question: Let's move to another aspect of  
:50:39 this, shaping of the superior condyles to extend the  
:50:43 articular surface back toward the patellar flange to  
:50:51 accommodate flexion of the femoral component relative to the  
:50:55 tibial component of at least 160 degrees. That's what I  
:51:00 want to focus on. You understand that?

:51:03 "Answer: Yes.

:51:03 "Question: Okay. We go back to my questions.  
:51:07 Do you recall that you had discussions with Dr. Scott and  
:51:11 Dr. Scuderi concerning this feature?

:51:14 "Answer: Yes.

:51:15 "Question: Who else would typically be present?

:51:19 "Answer: Always a development engineer. So  
:51:20 typically it would have been Mark Heldreth or Audrey  
:51:24 Beckman, sometimes Bob Hodorek would have been involved.

:51:28 "Question: Let's go to the next feature, same

Davis - depo.

:51:32 questions, spine/cam interactions where the cam moves down  
:51:38 during deep flexion between 130 and 160 degrees. Was this  
:51:43 feature also a subject of these conversations that you had  
:51:48 with Dr. Scott, Dr. Scuderi, Dr. Insall, and with an  
:51:52 engineer from Zimmer?

:51:54 "Answer: Yes.

:51:55 "Question: And would it also have been a dozen  
:51:58 or so conversations regarding this feature?

:52:00 "Answer: Yes.

:52:06 "Question: Why was a Zimmer engineer, Hodorek,  
:52:11 present during these conversations?

:52:14 "Answer: Well, you had to have an engineer  
:52:16 there to speak to the capability of designing something that  
:52:19 could accomplish that. It's all well and good to have a  
:52:23 market desire to accomplish it, and it's all well and good  
:52:27 to have physician input that says you have to be able to do  
:52:32 this; it all comes down to engineering. And you would not  
:52:37 have a development meeting ever without a development  
:52:43 engineer in the mix. I don't think at that point it would  
:52:47 even be considered a development meeting.

:52:49 "Question: The last feature I want to talk  
:52:51 about is the need for cam/spine mechanism and interaction  
:52:55 that allows for deeper flexion without causing subluxation.  
:53:01 Same question, do you recall discussing this feature with  
:53:08 the -- with Dr. Scott, Dr. Scuderi, Dr. Insall?

Davis - depo.

:53:13 "Answer: Yes.

:53:14 "Question: In the same meetings that you had  
:53:17 referred to earlier with respect to the other features?

:53:22 "Answer: Yes.

:53:23 "Question: Did these discussions that you  
:53:25 referred to about these features result in what we see here  
:53:34 in the claims that I asked you to read?

:53:37 "Answer: In large part, yes.

:53:38 "Question: Do you recall discussing with Drs.  
:53:42 Insall, Scott, and Scuderi using a modular component to  
:53:49 thicken the femoral condyle?

:53:55 "Answer: Yes.

:53:56 "Question: And was this a part of the same  
:53:58 dozen or so conversations you referred to in your earlier  
:54:04 testimony in response to questions about the first patent?

:54:09 "Answer: Yes, they were.

:54:10 "Question: So, again, it was the five of you,  
:54:13 six of you that sat around and discussed this feature, the  
:54:18 feature using a modular component to thicken the femoral  
:54:33 condyle?

:54:34 "Answer: At various points, yes.

:54:35 "Question: Do you recall discussing with Dr.  
:54:37 Scott, Dr. Scuderi, and Dr. Insall the concept of setting  
:54:42 rotational limits on the bearing to limit rotation?

:54:46 "Answer: Yes.

Davis - depo.

:54:47 "Question: Do you recall conversations with  
:54:52 Drs. Insall, Scott, and Scuderi on how to prevent the  
:54:56 spinout of the tibial tray utilizing a notch or a post?

:55:01 "Answer: Yes.

:55:09 "Question: Do you recall having conversations  
:55:11 with Dr. Scott or Scuderi regarding the placement of the  
:55:16 rotational limit notch?

:55:19 "Answer: Yes.

:55:19 "Question: Do you recall having discussions  
:55:21 with Dr. Scott, Dr. Scuderi, and Dr. Insall regarding  
:55:25 limiting the rotation to 50 degrees?

:55:28 "Answer: Yes.

:55:35 "Question: Now, you've told me that you do  
:55:38 remember specifically discussing these items that I just  
:55:40 enumerated with Dr. Scott, Scuderi, and Dr. Insall. Do you  
:55:45 remember specifically what any of them said about these  
:55:47 features which found their way into the patent that we've  
:55:53 marked as TD-24?

:55:58 "Answer: No, I don't.

:56:02 "Question: Did the discussions that you had  
:56:05 concerning these features that I enumerated result in what  
:56:08 you see here in the claims of the patent we've marked as  
:56:15 TD-24.

:56:16 "Answer: Yes.

:56:18 "Question: Do you know whether ISK contributed

Davis - depo.

:56:21 the concept of a posterior location of a stem locking screw?

:56:27 "Answer: I don't know that, no.

:56:28 "Question: Do you know whether the idea for the  
:56:31 screw-down originated with Dr. Scuderi?

:56:35 "Answer: I don't know that.

:56:38 "Question: Was Dr. Scuderi involved in it?

:56:42 "Answer: Not in the LPS, no.

:56:45 "Question: When Zimmer received recommendations  
:56:48 for design changes or product attributes from one of those  
:57:00 surgeons, one of those four, was it Zimmer's understanding  
:57:06 that that was an idea or concept coming from one or that it  
:57:12 was coming from ISK collectively?

:57:14 "Answer: I would say we typically know where it  
:57:17 was coming from and not always did they agree.

:57:21 "Question: Do you know what's required under  
:57:24 patent law to be an inventor of a patent?

:57:27 "Answer: No.

:57:27 "Question: Have you ever heard the phrase  
:57:34 conception in connection with a patent?

:57:36 "Answer: No.

:57:37 "Question: Have you ever reviewed the  
:57:38 prosecution history for the '729 patent?

:57:40 "Answer: No, I have not.

:57:41 "Question: When is the last time you reviewed  
:57:43 the '786 patent in its entirety?



Davis - depo.

:57:46 "Answer: Again, that would have been at its  
:57:47 issuance in 2002.

:57:50 "Question: Did you ever review the prosecution  
:57:53 history for the '786 patent?

:57:55 "Answer: No.

:57:55 "Question: When is the last time you reviewed  
:57:57 the entirety of the '283 patent?

:58:01 "Answer: Again, it would have been shortly  
:58:02 after its issuance in November of 2001.

:58:06 "Question: Did you ever review the prosecution  
:58:08 history for the '283 patent?

:58:10 "Answer: No, I did not.

:58:12 "Question: Do you believe that you should be  
:58:13 named as an inventor on the '729 patent?

:58:17 "Answer: No.

:58:17 "Question: So in your view, the mere fact that  
:58:21 you participated in design and development meetings was  
:58:24 insufficient for you to believe you should be an inventor on  
:58:27 the '729 patent. Is that right?

:58:29 "Answer: For me, yes.

:58:32 "Question: Do you believe you should be an  
:58:35 inventor of the '786 patent?

:58:37 "Answer: No.

:58:37 "Question: Do you believe that your role in the  
:58:40 design and development process helped make the eventual

Davis - depo.

:58:46 product better?

:58:49 "Answer: I believe so, yes.

:58:52 "Question: And that would be true with respect  
:58:54 to the LPS Flex and mobile?

:58:57 "Answer: Yes.

:58:58 "Question: And you don't believe that simply  
:59:00 making the product better through the design and development  
:59:03 process should make you an inventor on the '786 patent?

:59:08 "Answer: No.

:59:09 "Question: What about on the '729 patent?

:59:13 "Answer: Same answer.

:59:15 "Question: Do you believe you should be an  
:59:18 inventor on the '283?

:59:20 "Answer: No.

:59:20 "Question: Why not?

:59:27 "Answer: Same rationale.

:59:28 "Question: How many times over the years do you  
:59:31 believe you had conversations or interactions with Dr.  
:59:35 Insall?

:59:35 "Answer: More than 50, less than a hundred.

:59:39 "Question: Would you say you have a high  
:59:41 opinion of his integrity?

:59:46 "Answer: Extremely high, yes.

:59:48 "Question: High opinion of Dr. Insall's  
:59:50 character?

Davis - depo.

:59:53 "Answer: Yes.

:59:54 "Question: Do you believe that Dr. Insall would  
:59:56 take the ideas of others and represent them as his own?

:59:59 "Answer: No.

:00:04 "Question: Did Dr. Insall ever tell you that  
:00:08 Dr. Scott should be an inventor on the '729 patent?

:00:12 "Answer: We never discussed that, no.

:00:14 "Question: Did Dr. Insall ever tell you that  
:00:17 Dr. Scott should be an inventor on the '786 patent?

:00:21 "Answer: Again, we never discussed that, no.

:00:23 "Question: Did Dr. Insall ever tell you Dr.  
:00:26 Scott should be an inventor on the '283 patent?

:00:29 "Answer: No.

:00:29 "Question: Did Dr. Insall ever tell you Dr.  
:00:32 Scuderi should be an inventor on the '729 patent?

:00:35 "Answer: No. Again, we did not discuss that.

:00:38 "Question: Did Dr. Insall ever tell you Dr.  
:00:40 Scuderi should be an inventor on the '786 patent?

:00:43 "Answer: No.

:00:44 "Question: Did Dr. Insall ever tell you Dr.  
:00:46 Scuderi should be an inventor on the '283 patent?

:00:49 "Answer: No.

:00:50 "Question: To your knowledge, did Dr. Insall  
:00:54 tell anyone at Zimmer that Dr. Scott should be an inventor  
:00:57 on the '729 patent?

Davis - depo.

:00:59 "Answer: To my knowledge, no.

:01:00 "Question: To your knowledge, did Dr. Insall  
:01:03 tell anyone at Zimmer that Dr. Scott should be an inventor  
:01:07 on the '786 patent?

:01:09 "Answer: No.

:01:09 "Question: To your knowledge, did Dr. Insall  
:01:12 tell anyone at Zimmer that Dr. Scott should be an inventor  
:01:15 on the '283 patent?

:01:16 "Answer: No.

:01:17 "Question: To your knowledge, did Dr. Insall  
:01:20 tell anyone at Zimmer that Dr. Scuderi should be an inventor  
:01:23 on the '729 patent?

:01:24 "Answer: To my knowledge, no.

:01:25 "Question: To your knowledge, did Dr. Insall  
:01:27 tell anyone at Zimmer that Dr. Scuderi should be an inventor  
:01:30 on the '786 patent?

:01:32 "Answer: No.

:01:33 "Question: To your knowledge, did Dr. Insall  
:01:35 tell anyone at Zimmer that Dr. Scuderi should be an inventor  
:01:39 on the '283 patent?

:01:41 "Answer: No.

:01:42 "Question: You can put that aside. Now, do you  
:01:45 recall earlier that Mr. Friedman asked you about  
:01:47 conversations that you would have had with Dr. Scott or  
:02:03 Scuderi related to particular features of some of Zimmer's

Davis - depo.

:02:10 knee prostheses?

:02:12 "Answer: Yes.

:02:15 "Question: Do you remember him asking you  
:02:17 questions about the shaping of the superior condyles to  
:02:23 allow for increased flexion?

:02:25 "Answer: Yes.

:02:25 "Question: And I believe you testified earlier  
:02:28 that you had approximately ten conversations with Dr. Scott  
:02:30 and Scuderi on that point. Do I recall that correctly?

:02:34 "Answer: I believe so, yes.

:02:35 "Question: Okay. Let's walk through each of  
:02:37 those conversations so that I can understand what it was  
:02:43 that they said and when. So when was the first conversation  
:02:48 that you recall related to the shaping of the superior  
:02:51 condyles to allow for increased flexion?

:03:00 "Answer: I don't recall.

:03:03 "Question: But I thought you testified earlier  
:03:06 that you recall ten conversations. I'm just trying to get  
:03:09 the details of these things. So when was the first one?

:03:13 "Answer: I don't remember.

:03:13 "Question: Well, now in this first  
:03:16 conversation, do you recall everybody that was present at  
:03:19 the meeting?

:03:19 "Answer: No.

:03:20 "Question: For this first meeting, do you know

Davis - depo.

:03:23 any of the specific details about what was discussed in  
:03:27 relationship to shaping of the superior condyles to allow  
:03:29 for increased flexion?

:03:31 "Answer: No.

:03:33 "Question: Do you recall any inputs that  
:03:35 anybody provided at this first meeting?

:03:38 "Answer: Not specifically, no.

:03:39 "Question: Well, let's try the second meeting.  
:03:43 When was the second meeting related to shaping of the  
:03:48 superior condyles to allow for increased flexion?

:03:53 "Answer: I could say it was after the first  
:03:54 meeting, but that's probably not what you're looking for.

:03:58 "Question: Can you give me a date?

:04:00 "Answer: Sometime after the first meeting.

:04:02 "Question: Let's go back to this second meeting  
:04:05 about shaping of the superior condyles to allow for  
:04:08 increased flexion. Who do you specifically recall being  
:04:11 present at that meeting?

:04:13 "Answer: Again, I have general recollection of  
:04:17 the meetings that took place in Dr. Insall's office made an  
:04:22 impact on me because of my respect for Dr. Insall and Dr.  
:04:26 Scott and Dr. Scuderi. I don't recall what day it was. I  
:04:31 don't recall the exact participants at that meeting.

:04:33 "Question: Would those design discussions have  
:04:36 been reflected in meeting minute notes?

Davis - depo.

:04:38 "Answer: I guess they typically would have  
:04:40 been. Those would have been performed and distributed by  
:04:42 the development engineers at that time. So Audrey Beckman  
:04:46 would have been, later Mark Heldreth would have been  
:04:50 responsibility for putting out meeting minutes. And, in  
:04:53 fact, we did look through several of those through testimony  
:04:56 today.

:04:56 "Question: And if you wanted to try to identify  
:04:58 who provided particular inputs or contributions, would you  
:05:02 go look at those design meeting minutes to try to figure it  
:05:05 out?

:05:06 "Answer: I believe you could, yes. As years  
:05:09 went on, we made a particular point of ensuring that we  
:05:13 could. I don't know when that practice became, you know,  
:05:18 rule.

:05:18 "Question: Do you recall any details about the  
:05:20 third meeting that you had?

:05:22 "Answer: No.

:05:22 "Question: Any specific recollection of the  
:05:24 participants?

:05:25 "Answer: No. Again, it was typically though  
:05:29 always Dr. Scott and Dr. Insall and Dr. Scuderi.

:05:34 "Question: Would the meeting minutes reflect  
:05:37 the parameters of those meetings?

:05:40 "Answer: Yes, they would.

Davis - depo.

:05:41 "Question: What about the fourth conversation,  
:05:43 do you recall any specific details about that?

:05:45 "Answer: No. I can save you time. If you want  
:05:52 to go through four through six or four through ten, we're  
:05:55 going to have the same dialogue.

:05:57 "Question: Let me break that up. You generally  
:06:00 recall that there were ten meetings, but you have no  
:06:02 specific recollection as to when they occurred. Correct?

:06:05 "Answer: Yes.

:06:05 "Question: You have no specific recollection  
:06:07 regarding these ten meetings as to the participants for  
:06:10 those specific meetings. Correct?

:06:12 "Answer: Not each of those meetings, no.

:06:14 "Question: And you also have no specific  
:06:17 recollection of the conversations that occurred at those ten  
:06:20 meetings that you generally recall. Is that correct?

:06:22 "Answer: That's correct.

:06:23 "Question: And now in having discussions with  
:06:26 Mr. Friedman, you talked about roughly the same number of  
:06:30 meetings for a number of different points, shaping of the  
:06:36 superior condyle, spine-cam interactions, cam-spine  
:06:40 mechanisms. Do you recall that?

:06:42 "Answer: Yes.

:06:43 "Question: Let's take them one at a time just  
:06:45 so that I don't have to repeat if question.



Davis - depo.

:06:47 "When you're referring to the meetings were  
:06:50 shaping of the superior condyles to extend the articular  
:06:54 surface back toward the patellar flange to accommodate flex  
:06:58 of the femoral component of at least 160 degrees, you're  
:07:03 referring to the same meetings that we just discussed where  
:07:06 you don't have recall of specific detail. Is that right?

:07:08 "Answer: That's correct. All these design  
:07:11 parameters would have been discussed at the same meetings.

:07:13 "Question: And when you referred or testified  
:07:15 earlier about the discussions of the spine-cam interactions  
:07:18 where the cam moves down during deep flex between 150 and  
:07:22 160 degrees, you're also referring to these same meetings  
:07:25 which you don't recall any specific details about. Is that  
:07:28 right?

:07:28 "Answer: Yes.

:07:30 "Question: When you testified earlier about the  
:07:31 cam-spine mechanism and interactions that allows for deeper  
:07:36 flexion without causing subluxation, you're referring to the  
:07:39 same ten meetings that you don't have specific recollection  
:07:42 about. Is that right?

:07:43 "Answer: Yes.

:07:43 "Question: Also earlier when you testified  
:07:45 about the modular component to thicken femoral condyles,  
:07:50 you're referring to the same ten meetings, wherein you said  
:07:54 a dozen or so at that point, but you don't recall the

Davis - depo.

:07:57 specific details of any of those meetings. Is that right?

:08:03 "Answer: Correct.

:08:03 "Question: Earlier when you testified about  
:08:07 discussions of setting rotational limits on the bearing to  
:08:11 limit rotation, you were referring to the same meetings that  
:08:14 you don't have any specific recollection about. Is that  
:08:17 correct?

:08:17 "Answer: Yes.

:08:18 "Question: Earlier when you testified about  
:08:20 discussions to prevent spinout of the tibial tray utilizing  
:08:25 a notch or post, you were referring to the same meetings  
:08:28 that you don't have any specific recollection about?

:08:31 "Answer: Yes.

:08:31 "Question: Earlier when you testified about  
:08:33 limiting the rotation to 50 degrees, you were also referring  
:08:37 to these same meetings that you don't have any specific  
:08:40 recollection about?

:08:41 "Answer: That's correct.

:08:42 "Question: Earlier when you testified about the  
:08:44 need for a vent hole in the poly or articular surface, you  
:08:48 were referring to the same meetings that you don't have any  
:08:50 specific recollection about?

:08:51 "Answer: Yes.

:08:52 "Question: Earlier when you testified about the  
:08:54 trunnion, you were referring to the same meetings that you

Davis - depo.

:08:57 don't have any specific recollection about?

:09:00 "Answer: Yes.

:09:01 "Question: Earlier when you talked about the  
:09:03 use of a fastener or screw hole to be used to hold the poly  
:09:07 or articular surface in place with respect to the tibial  
:09:11 plateau, you were referring to the same meetings that you  
:09:14 don't have any specific recollection about. Right?

:09:17 "Answer: Yes.

:09:17 "Question: Do you have any specific  
:09:19 recollection of Dr. Scott providing input into the extended  
:09:23 posterior condyles?

:09:24 "Answer: No, I stated that earlier.

:09:28 "Question: Do you have any specific  
:09:29 recollection of Dr. Scuderi providing input into the  
:09:33 extended posterior condyles?

:09:35 "Answer: No.

:09:36 "Question: Take a look at No. 2, which is  
:09:39 improve the cam-spine mechanism. Do you have any specific  
:09:43 recollection of Dr. Scott providing input into the improved  
:09:46 cam-spine mechanism?

:09:47 "Answer: No.

:09:49 "Question: Do you have any specific  
:09:51 recollection of Dr. Scuderi providing any input into the  
:09:56 improved cam-spine mechanism?

:09:58 "Answer: No.

Davis - depo.

:09:58 "Question: Do you consider Dr. Scott a friend?

:10:00 "Answer: Yes.

:10:00 "Question: Do you consider Dr. Scuderi a  
:10:02 friend?

:10:03 "Answer: Yes.

:10:03 "Question: How did your employment end at  
:10:06 Zimmer?

:10:13 "Answer: I was fired.

:10:13 "Question: It's fair to say that you're not  
:10:16 happy with Zimmer right now. Correct?

:10:18 "Answer: Correct."

:10:28 MS. JACOBS LOUDEN: Your Honor, for the record,  
:10:30 of the 38 minutes and 53 seconds of designation, 17 minutes  
:10:35 and 26 seconds were plaintiffs' designations, 21 minutes and  
:10:40 21 seconds were defendants' designations.

:10:43 THE COURT: Okay.

:10:43 Counsel, you are keeping track of one another's  
:10:46 time, I assume.

:10:47 MS. JACOBS LOUDEN: Yes, we are.

:10:50 THE COURT: Next witness.

:10:51 MR. FRIEDMAN: I would like to call as our next  
:10:58 witness Dr. John Callaghan.

:11:14 ... JOHN CALLAGHAN, having been duly sworn as  
as a witness, was examined and testified as  
:13:08 follows ...

Davis - depo.

**DIRECT EXAMINATION**

**BY MR. FRIEDMAN:**

Q. Good afternoon, Dr. Callaghan.

A. Good afternoon.

Q. For the record, would you please state and spell your full name?

A. It's John Joseph Callaghan, last name is

C-a-l-l-a-g-h-a-n.

Q. And what is your current profession, Dr. Callaghan?

A. My current profession is I am a medical doctor. I actually have three different parts to that.

Q. Let's take them one by one. What is the first part?

A. So I am an orthopedic surgeon.

Q. What is the second part?

A. I am a professor at university.

Q. And what is the third part?

A. I am an implant designer both of these and hips.

Q. Before we get into the details of those three activities, can you please tell us where you currently live?

A. I currently live in Iowa City, Iowa.

Q. And where do you practice medicine?

A. I practice medicine at the University of Iowa.

Q. You live with your family there?

A. I live with my family, my wife Kim and a couple children who actually are gone most of the time now.

Callaghan - direct

:14:25 Q. How did you first get interested in orthopedic  
:14:30 medicine?

:14:33 A. Probably similar to a lot of people. I played a lot  
:14:36 of sports in high school. I had knee injuries, had to see  
:14:39 orthopedic surgeons. I think actually from that period of  
:14:41 time onwards, I had some interest in it.

:14:45 Q. What did you do after you graduated from high school?

:14:49 A. I attended the University of Notre Dame.

:14:52 Q. And at the University of Notre Dame, what did you  
:14:55 study?

:14:56 A. At Notre Dame I studied both engineering and other  
:15:05 aspects of science. I left there after three years. So I  
:15:09 didn't get a degree until later.

:15:10 Q. And maybe you could explain why you left after three  
:15:13 years and why it is you didn't get your degree until later?

:15:17 A. Yes. So I had the opportunity to go to medical school  
:15:22 a year early. So I decided to take that option. I had some  
:15:27 military commitment later on that I wanted to finish up. So  
:15:29 I, after three years, I went from Notre Dame to medical  
:15:32 school.

:15:33 Q. And what medical school did you go to?

:15:35 A. I went to Loyola University Medical School in Chicago.

:15:39 Q. And when did you receive your medical degree from  
:15:43 Loyola?

:15:45 A. So at that time, they had a three-year program. So I

Callaghan - direct

:15:48 did three years, in three years I got my medical degree and  
:15:51 that's when Notre Dame also gave me my Bachelor of Science,  
:15:55 they retroacted it to '76.

:16:03 Q. After graduating from Loyola, you did an internship?

:16:07 A. I did.

:16:08 Q. And then you did a residency?

:16:11 A. That's correct.

:16:11 Q. Where did you do the residency?

:16:15 A. I did both the internship and that residency at the  
:16:20 University of Iowa.

:16:21 Q. And during your residency, what is it you focused on?

:16:28 A. During that time I really focused on all aspects of  
:16:31 orthopedic surgery. Did some lab work and research. But  
:16:36 basically, it was a five-year residency in learning general,  
:16:40 all aspects of orthopedic surgery.

:16:42 Q. Following your residency at the University of Iowa,  
:16:48 did you do a fellowship anywhere?

:16:50 A. I did do a fellowship after I was at the University of  
:16:54 Iowa. I went to New York City, and did a fellowship at the  
:16:57 Hospital for Special Surgery.

:17:00 Q. During your fellowship at Hospital for Special Surgery  
:17:06 in New York, what did you focus there?

:17:08 A. There I focused on lower extremity adult hip and knee  
:17:12 reconstruction.

:17:14 Q. Now, after your fellowship, what did you do?

Callaghan - direct

:17:19 A. After my fellowship, as I said before, I actually have  
:17:24 had a military commitment from ROTC in college, so I went to  
:17:29 Walter Reed Army Medical Center, where I was on the staff of  
:17:33 Uniformed Services University Health Sciences at the same  
:17:38 time.

:17:38 Q. Now, I have also handed you, in addition to a  
:17:47 notebook, a copy of your CV.

:17:53 A. Yes.

:17:59 MR. FRIEDMAN: Your Honor, this does not have a  
:18:01 document number yet. I need to assign a document number to  
:18:05 it for the record.

:18:06 MR. HIGER: We don't have a problem with the  
:18:08 witness referring to this document, Your Honor. But we do  
:18:10 object to this coming into evidence.

:18:12 THE COURT: I don't -- you don't need it in  
:18:16 evidence, do you?

:18:16 MR. FRIEDMAN: No, Your Honor. In fact, tell  
:18:18 you what. I will put it aside.

:18:20 THE COURT: You can reference it, if you like.  
:18:23 I have it. I am reading it.

:18:26 MR. FRIEDMAN: Okay.

:18:26 BY MR. FRIEDMAN:

:18:30 Q. I would like to discuss a little more about your  
:18:34 experiences. You said you have three jobs. I want to start  
:18:41 with your first job. That's an orthopedic surgeon?



Callaghan - direct

- :18:44 A. That's correct.
- :18:44 Q. And where are you licensed to practice medicine?
- :18:49 A. Presently, I am licensed to practice medicine in Iowa.
- :18:52 Q. Have you been licensed elsewhere?
- :18:55 A. I was. When I was in New York, I had a license there.
- :19:00 We didn't discuss it, but I was at Duke University for a
- :19:03 couple of years on the faculty. And I also had a license in
- :19:06 North Carolina. I gave those up. I voluntarily gave them
- :19:09 up when I went to Iowa.
- :19:11 Q. Now, as an orthopedic surgeon, do you see patients and
- :19:17 perform surgeries?
- :19:18 A. I do.
- :19:19 Q. Approximately how many patients do you see per year?
- :19:23 A. So in that job I concentrate mostly on adult hip and
- :19:27 knee reconstructive surgery, seeing 4,000, 4,500 -- 1500
- :19:33 patients a year, and maybe -- I would say 1500.
- :19:37 Q. How many patient operations do you do annually?
- :19:43 A. I do in excess of 250, probably now more upwards of
- :19:48 300-plus.
- :19:49 Q. During the course of your career, approximately how
- :19:55 many knee and hip replacements have you done?
- :19:58 A. It's hard to say. I didn't go back and specifically
- :20:01 look. But I bet somewhere around 7500 knee and hip
- :20:06 replacement surgeries.
- :20:07 Q. Now, the second job you referred to was a job as

Callaghan - direct

:20:12 professor. Where are you currently serving as a professor?

:20:18 A. So I am a professor both in the College of Medicine at  
:20:22 the University of Iowa and then in addition I am a professor  
:20:26 in biomedical engineering.

:20:30 Q. So you are on both faculties at University of Iowa?

:20:33 A. Both faculties. And I have a professorship in both  
:20:37 departments.

:20:37 Q. And do you have any affiliation with any hospitals in  
:20:43 Iowa City, Iowa?

:20:46 A. I am obviously at the university hospital, which is  
:20:48 the hospital at the university. Then we also have a  
:20:51 Veterans Administration Hospital. And I am very active at  
:20:55 that, too.

:20:56 Q. Doing orthopedic surgery?

:20:58 A. All -- mostly adult hip and knee reconstructive  
:21:01 surgery. I do take trauma calls. So I do trauma, too.

:21:05 Q. Do you hold any chairs, any endowed chairs at the  
:21:10 University of Iowa?

:21:11 A. I do. I sit in the Lawrence and Marilyn Dure  
:21:18 (phonetic) Chair in hip surgery and research.

:21:21 Q. Now, you say you are on two faculties, the medical  
:21:26 faculty and the biomedical faculty.

:21:28 Let's take them one by one. Can you give us  
:21:34 some examples of courses you teach in your capacity on the  
:21:39 medical faculty?

Callaghan - direct

A. Sure. On the medical faculty, I spend most of my time teaching students and residents and fellows who come through our orthopedic department, some formal lectures to medical students, some formal lectures to residents and obviously teaching them the operating room. And that's most of the teaching I do, as far as the college of medicine teaching.

Q. And what about as of a member of the faculty of biomedical engineering?

A. So as a member of that faculty, I give lectures to undergraduates, as well as graduate students in engineering. I oversee my laboratory, which is a bioengineering type laboratory. And in that laboratory, we have students and graduate students, a lot of M.S. and Ph.D. graduate students. We do projects with those people. I sit on these committees, things like that.

Q. What types of courses do you teach as a member of the faculty of biomedical engineering?

A. They are really related to clinical biomechanics. So it would be hip and knee implant design and its relationship to clinical problems that we see.

Q. Let's just move to the area of publications for a moment. How many articles have you written?

A. I have written quite extensively. I don't know what the last count here was. It has to be over 280 true peer-reviewed articles. Another 180 or so non-peer-reviewed

Callaghan - direct

:23:31 articles. Textbooks, you know, eight or ten textbooks. I  
:23:38 actually compete with Dr. Scott's Knee textbook. We have an  
:23:41 adult knee textbook ourselves.

:23:44 Q. What is the name of your book?

:23:45 A. It's call The Adult Knee.

:23:47 Q. And could you just explain a little bit about this  
:23:51 followup study you are doing in your laboratory that you  
:23:54 talked about?

:23:55 A. Yes. So the one area of -- I would say the world  
:24:01 expertise that we really have is on long-term followup  
:24:05 studies of the implants, fixed-bearing, mobile-bearing, et  
:24:08 cetera. And I think those long-term studies are really  
:24:13 significant from the standpoint of understanding what works  
:24:16 and doesn't work in knee implant designing and what type of  
:24:21 complications we see over 20-year followup periods with  
:24:25 those designs.

:24:25 Q. You said that the third aspect of what you do is as a  
:24:31 knee implant developer. What does that involve?

:24:34 A. So probably since about -- I didn't look up the exact  
:24:40 date, but probably since about 1994, I have been involved in  
:24:44 designing knee implants.

:24:47 Q. And are you currently working as a developer and  
:24:53 design surgeon with regard to knee implants for any  
:24:57 manufacturer?

:24:57 A. Knee implants, yes. I originally started out, Johnson

Callaghan - direct

:25:03 & Johnson was a separate company. So I did knee implant  
:25:06 design with that company. They bought Depew, which is now  
:25:11 called the Johnson & Johnson Company. And since that  
:25:15 merger, I have been working with Depew, exclusively as far  
:25:20 as implant design.

:25:21 Q. And is Depew a competitor of Zimmer?

:25:26 A. It is.

:25:26 Q. And, in fact, have you done any work for Zimmer in the  
:25:30 past?

:25:33 A. If you look at my CV, I think even back to the early  
:25:37 '90s I did a lot of research work with Zimmer. And when I  
:25:40 was at Duke University, I did a lot of research work with  
:25:44 Zimmer.

:25:44 Q. Now, have you served in any leadership positions in  
:25:50 any professional organizations?

:25:52 A. I have.

:25:52 Q. Can you tell us about that?

:25:55 A. Yes. So most recently, I was president of the  
:25:58 American Academy of Orthopedic Surgeons. That's our largest  
:26:02 orthopedic surgery organization in the country. We have  
:26:06 38,000 members. But before that I also was president of the  
:26:11 American Association of Hip and Knee Surgeons, the Hip  
:26:15 Society, I have been on the board of the Knee Society, a  
:26:19 number of organizations. But I think for this discussion,  
:26:23 that probably gives you an idea.

Callaghan - direct

Q. Now, do you testify frequently as an expert witness?

A. No. I am not a professional expert, as you can see, I do a few other things.

Q. I am pretty amazed. It makes me feel very insignificant. I can't get done what I have to get done.

How many times have you testified?

A. You know, I tried to look it up the best I could. It's five or less.

Q. Over the course of your career?

A. Over, yes, 28 years in practice.

Q. In what types of cases?

A. Those were all malpractice-related cases. Never on anything related to patents.

Q. Now, what are you charging for your work in this case?

A. I am charging for my work in this case, I think it's \$900 -- it is. It is \$900 an hour for depositions and all of the -- not depositions. For all of the reading of documents and preparing my report, and then \$1100 for a deposition, and trial.

Q. How did you arrive at those hourly rates?

A. As I said, I don't do much of this work. These are actually our university standards. It was related to what the universities recommends, those charges.

Q. They set the rates?

A. They set rates, yes.

Callaghan - direct

:27:54 Q. Do you know Dr. Scott?

:27:56 A. I do know Dr. Scott.

:27:58 Q. Do you know Dr. Scuderi?

:28:00 A. I do know Dr. Scuderi.

:28:08 Q. I presume over the years you had many interactions  
:28:12 with both of them?

:28:13 A. Yes. Well, I mean, we are all kind of from the  
:28:18 Hospital for Special Surgery alumni group. I probably met  
:28:22 Dr. Scott when I was a fellow there in 1983-84 and probably  
:28:27 Dr. Scuderi, I think he was about 1988, he was a fellow  
:28:33 there. I used to go back a lot during that period of time.

:28:37 Q. Would you consider them to be professional colleagues?

:28:43 A. I would, absolutely, consider them to be professional  
:28:45 colleagues of mine.

:28:46 Q. Do you socialize with them outside of the work  
:28:49 context?

:28:49 A. Mostly just at meetings. You know, there is social  
:28:55 things at meetings. But other than that, after sometimes  
:29:00 during courses, there is social events, that has really been  
:29:04 the context from a social standpoint.

:29:06 Q. In the last five years or so, how frequently have you  
:29:10 had interactions with Dr. Scott and Dr. Scuderi?

:29:14 A. You know, it was interesting. When watching Mr. Davis  
:29:17 there, it's hard to say. But especially in my deposition I  
:29:20 tried to at least keep it as factual as I could. So two

Callaghan - direct

:29:24 times a year for sure we would meet at our American Academy  
:29:30 meeting and our Knee Society meeting. Definitely those two  
:29:33 times. I might be in New York and see them sometimes or we  
:29:36 might be at another meeting. But that is really the context  
:29:39 of it.

:29:39 Q. Have you ever discussed your work in this case with  
:29:43 Dr. Scott?

:29:45 A. I have not.

:29:46 Q. Have you ever discussed your work in this case with  
:29:48 Dr. Scuderi?

:29:49 A. I have not.

:29:50 Q. Now, do you consider yourself to be an expert in the  
:29:57 field of knee implant design and development?

:30:02 A. Yes, I do. You know, there are very few people with  
:30:08 the experience and the qualifications of someone like  
:30:14 myself. As far as knee implantation and designing and  
:30:21 developing knee replacements, in addition to kind of seeing  
:30:25 it through this whole process where, in design teams,  
:30:32 sometimes leadership and organizational skills are  
:30:35 necessary, and I think that's obviously one of my, you know,  
:30:38 strong suits, and I think when implant, knee implant  
:30:43 manufacturing companies like Zimmer or Depew, who I do my  
:30:47 consultation work for, when they are looking at designing  
:30:53 new implant systems, they go to this limited number of  
:30:57 people, like ourselves, who do this type of work and who can



Callaghan - direct

try to help them to design a new implant system or concept.

That's how it works out, basically.

Q. What were you asked to do in this case?

A. So in this case, I was asked to review documents, deposition testimonies, other materials related to the conception and development of an implant and its design, and as it related to the devices that have been discussed here, and to form conclusions as to whether or not Dr. Scott and Dr. Scuderi contributed to the claims of the patents that we are talking about.

Q. Were you asked to provide any opinions about whether Dr. Scott or Dr. Scuderi should be listed as inventors on the patents?

A. No, I wasn't. I am not a lawyer, I am not a patent attorney. My understanding, Judge, is that that is what you are going to do, is to make that decision.

THE COURT: Pretty much.

BY MR. FRIEDMAN:

Q. In preparing for this case, did you read the three patents that are at issue?

A. I did.

Q. More than once?

A. A number of times, yes.

Q. Are you confident that you were able to understand them?

Callaghan - direct

:32:58 A. Yes. You know, as I said, I am not really an expert  
:33:02 in that field. I never would claim to be. The hardest part  
:33:06 I had in just getting to the point of really being able to  
:33:10 totally understand them, I had to take the medical  
:33:14 terminology we use as surgeons and differentiate that from  
:33:19 the terminology in claims.

:33:21 But if you get to that point, and if you get to  
:33:26 the point, also, of understanding the way they are set up,  
:33:32 all the way through the figures and then the claims being  
:33:36 different, et cetera, et cetera, once you get to that point,  
:33:39 I think that the terminology in the claims is something that  
:33:43 I understand.

:33:45 Q. And did you form an opinion by your review of the  
:33:49 materials you described as to whether Dr. Scott and Dr.  
:33:53 Scuderi contributed to what is claimed in the patents?

:33:58 A. So after -- with my understanding of the design  
:34:04 process, the design process in the nineties, especially,  
:34:09 with my own experience, which has been similar, with the  
:34:15 documents that I have looked at, looking at the patents,  
:34:20 looking at medical brochures from Zimmer, looking at all the  
:34:26 documents that I looked at, I feel strongly that Dr. Scott  
:34:31 and Dr. Scuderi did contribute to the claims in those  
:34:35 patents.

:34:35 Q. And those materials, that wealth of materials that you  
:34:38 just referred to, were materials that you obtained from my

Callaghan - direct

law firm?

A. That's correct.

Q. Now, attached to your expert report, there is an exhibit, Exhibit B, that lists a number of documents?

A. Where would that be? Is it in here somewhere?

I have seen Exhibit B.

Q. My point is simply this: Does Exhibit B to your report list those documents that you reviewed that were furnished to you?

A. It does. You know, I have read a couple other depositions and a couple other things after that, all of which have been talked about or presented to me. But it represents at the time that I did my expert report exactly what I used to make that expert report.

Q. Now, after you reached the conclusions that you reached in this prior art, did you write an expert report?

A. I did.

Q. Did you write it yourself or with somebody else? How did the report evolve?

A. The way the report evolved is that I drafted an outline based on all those documents that I read in Exhibit B. Counsel then looked at that outline. We called each other, talked about it. We tried to put it into language that would be appropriate for the Court. Went back with a few edits, and then it ends up being what I believe and what

Callaghan - direct

my testimony was in that report.

Q. All of the documents that you referred to, the notes, the memos, all of the documents listed in Exhibit B, the depositions and so forth, did you read all that yourself?

A. I did read all that myself, yes.

Q. Now, I want to move to a different subject area, Dr. Callaghan. I would like to begin asking you questions about the process followed for designing a knee implant.

Based upon your experience, can you explain to the Court people having what types of skill sets are involved in the design and development of knee implants?

A. Yes. Judge, I don't mean to be repetitive. Mr. Davis did an excellent job of articulating it. But it would involve surgeons, design engineers, cadaver designers who put these on computers, sometimes marketing people and sometimes salespeople from the companies.

Q. In your opinion and based upon your experience, can a new implant device be successfully designed only by an engineer?

A. You know, in all due respect to engineers, no. I myself have an engineering background. I teach engineers. I help them get their degrees. Many of them are actually employed by Zimmer and Depew. But I can tell you that they just don't have the medical knowledge to understand the physiology, the kinesiology, that goes on in the human body.

Callaghan - direct

:38:19 They don't have the hands-on experience of placing implants,  
:38:24 feeling what those feel like in patients. Once again, I say  
:38:28 that with due respect, because it's obviously a field that I  
:38:33 am involved in.

:38:33 Q. How does a surgeon such as yourself have the hands-on  
:38:38 knowledge and experience about knee implant designs that an  
:38:41 engineer typically doesn't have?

:38:43 A. You know, I think it goes to the real-life experience.  
:38:48 I think a lot of people think all we do is install implants  
:38:52 and then close up the wound and off the patient goes. But  
:38:57 there is a lot more to that process. We put the implant in,  
:39:02 we then have to see how it feels in that individual patient,  
:39:06 how it moves in that individual patient, how it rotates in  
:39:09 that individual patient.

:39:11 We have to make interoperative modifications.  
:39:14 Sometimes we change out a design. We put in different types  
:39:17 of polyethylene or different amounts are constrained and  
:39:22 it's really only someone who has that type of expertise that  
:39:25 can do it. We almost have each individual patient testing  
:39:30 out individual concepts and design. And you saw that a  
:39:35 little bit in what Mr. Davis was talking about.

:39:37 Q. From your experience, what does the -- what role does  
:39:45 the developing surgeon, also called the design surgeon, play  
:39:49 in the actual design of implant devices?

:39:53 A. Once again, Mr. Davis brought up a lot of these

Callaghan - direct

:39:55 things, I will make it very brief. But basically, the  
:40:00 surgeon from their -- taking care of clinical patients,  
:40:04 recognizes there is problems with the designs that are  
:40:06 currently out there. Then we come up with our own ideas  
:40:11 about how we can improve on those or make those better.  
:40:15 With the companies, we decide that it's a worthwhile  
:40:19 venture, it has to be a worthwhile venture for the  
:40:22 companies, as well as a worthwhile venture for us.

:40:25 Then we get together and brain-storm, coming up  
:40:29 with potential design criteria. Then there is no question  
:40:32 that the engineers themselves have to develop these  
:40:36 prototypes for us, so that we can put them in the body.  
:40:39 Then we check them in the body. In the past, the engineers  
:40:46 could be in the operating rooms a lot with us, it is not as  
:40:51 much that way today with HIPAA issues.

:40:53 We then talk about what needs to be done, the  
:40:58 design engineer -- the surgeon is the only one that can tell  
:41:02 you, you got to take off a little here, a little there.  
:41:05 Then we go through that collaborative iterative process with  
:41:09 them as well, in trying to come up with a final design.  
:41:14 That's it.

:41:15 Q. Could you briefly describe from your point of view  
:41:19 what a cadaver study is, although we have heard testimony so  
:41:23 we will keep that short, but why it is important in the  
:41:26 development of a knee implant device?

Callaghan - direct

:41:28 A. Sure. Because, especially when you have these  
:41:31 prototypes, you can't really implant them in patients all  
:41:35 the time. There is some that you can. But a cadaver gives  
:41:39 us a chance where not only we can implant it in them, but it  
:41:43 gives us time to sit there and discuss it all. If you are  
:41:46 operating on a patient and they are laid out and open, to  
:41:49 sit in and spend a bunch of time talking about little  
:41:53 nuances, I don't know if it is appropriate, even. But the  
:41:56 thing is, in a cadaver lab, you can take whatever time you  
:42:00 want, you can put those things in. You can move them  
:42:04 around. You can talk about what you are going to do. You  
:42:09 can cut off pieces of bone.

:42:11 This was all described in some of the documents  
:42:13 that are here before the Court. And it's just a place where  
:42:16 you can do it a lot in a lot easier atmosphere. Believe me,  
:42:21 you got to do it interoperatively, too. But that's what the  
:42:26 cadaver experience let's you do.

:42:28 Q. What does the interoperative experience let you do?  
:42:32 First of all, what is the interoperative experience?

:42:35 A. So the interoperative experience is, much as Mr. Davis  
:42:40 described, the company would bring in these prototypes, you  
:42:44 would size them up, sometimes you could just use some  
:42:48 instruments to see what the sizing of that particular  
:42:52 interoperative femur is, then figure out one of these  
:42:55 prototypes that will fit over that.

Callaghan - direct

:42:57                   And then you put that prototype on, whether it  
:43:01                   be those condylar changes or that cam change or whatever,  
:43:05                   and just see how the range of motion in that patient, how it  
:43:09                   interacted with that individual anatomy with that patient's  
:43:14                   ligaments, et cetera.

:43:15           Q.       When did you -- when you do these interoperative  
:43:21                   surgeries, where, typically, are the companies' engineers  
:43:26                   located?

:43:26           A.       So, you know, it's changed over the years. As I said,  
:43:29                   in the nineties, they would be, you know, relatively close  
:43:33                   distance, within feet of you. Sometimes you could let them  
:43:36                   peek in closer if you had something you really had to do.  
:43:39                   Today, it's changed a lot with HIPAA regulations.

:43:44           Q.       Now, when did you start doing knee design work?

:43:50           A.       So I initially started in the implant design back in  
:43:56                   the mid-nineties, '93-94 time frame.

:43:59           Q.       Now, are there any similarities between your  
:44:08                   experience with knee design and development in the 1990s and  
:44:12                   what you observed by reviewing the wealth of materials that  
:44:16                   were provided to you in this case?

:44:18           A.       You know, I had the opportunity to sit back there  
:44:20                   today and listen to the testimony and it's almost like a  
:44:23                   deja vu, because the experiences that they were having at  
:44:28                   ISK were the same experiences that those involved in the  
:44:33                   designs that I was developing were doing. You know, do you



Callaghan - direct

:44:39 want me to articulate more on that?

:44:41 Q. Please.

:44:41 A. You sit there, you brainstorm over ideas, the engineer  
:44:44 is working with the surgeons. We were all pretty good  
:44:48 friends in those days. It was more us working as a team,  
:44:54 trying to get projects completed in ways that we could help  
:44:58 patients better. And the concept of having formal  
:45:02 documentation of these things just was not there, Judge. I  
:45:06 know it's hard to believe. But it wasn't the main purpose,  
:45:09 at least for us as designing surgeons, I can tell you, I  
:45:13 don't care where my idea went, as long as it, you know,  
:45:16 helped us to the end goal, which was designing a better  
:45:19 implant, the implant to put in our patients.

:45:23 You saw that -- I don't need to reiterate any of  
:45:26 that. You saw it all just in the last time period that I  
:45:31 have been around in here.

:45:32 Q. And as a result of your review of the documents in  
:45:38 this case, including the depositions, were you able to  
:45:42 understand what was going on at ISK during that period in  
:45:46 the mid-1990s?

:45:53 A. One area we didn't talk about, obviously, I knew John  
:45:57 Insall very well, too. He was one of my teachers at Special  
:46:01 Surgery. During the nineties, I would go to New York at  
:46:08 least twice a year. I would always go over to ISK, because  
:46:12 I was designing the same type of implants that John Insall

Callaghan - direct

:46:14 and his team, Dr. Scott, Dr. Scuderi were designing, both  
:46:18 fixed and mobile-bearing knees. I was a PS knee guy,  
:46:23 posterior stabilized knee guy, like they were. So it was a  
:46:28 great interaction.

:46:32 Dr. Insall and I collaborated on one paper I  
:46:36 know for sure about mobile-bearing knees.

:46:38 Anyway, that's the way it was. I understood the  
:46:43 interaction that you saw there and that Davis talked about,  
:46:48 how those four guys really worked in unison and I think it  
:46:54 was very similar to the description that he had of, you  
:47:01 didn't really know or care who had the idea or part of the  
:47:06 idea because you molded that into what the real idea was  
:47:11 going to be.

:47:11 That's the way I see it.

:47:18 Q. Now, in the course of this design and development  
:47:21 process at a place like ISK, would the developer or design  
:47:29 surgeon typically keep detailed notes of their brainstorming  
:47:34 sessions in the nineties?

:47:35 A. You know, just like I had said before, you know,  
:47:40 whether it's our naivete or whatever, our interests were in  
:47:46 getting product out, to have something better that we could  
:47:50 put in people. That was where all of our work went. We  
:47:55 weren't patent lawyers. We didn't understand patents. We  
:47:58 weren't concerned about patents. We were concerned about  
:48:03 getting the work done, getting new implants. Sometimes we

Callaghan - direct

:48:06 weren't happy with the implants we were putting in. So it  
:48:11 was to our benefit to get something out as quickly as we  
:48:15 could just so that for our patients it would be helpful.

:48:17 Q. Was there anything in the documents that you reviewed  
:48:21 that would show the way that ISK worked or the way that ISK  
:48:25 and Zimmer worked together that were different than from  
:48:31 what you yourself were experiencing?

:48:32 A. No. It was exactly the same. It was exactly the  
:48:35 same. There is one difference. I am not going to say all  
:48:40 of us were jealous, but we were in a way because at ISK, in  
:48:45 fairness to Zimmer, they have a pretty good competitive edge  
:48:48 that way. They had these three surgeons right there. They  
:48:51 are in their clinicals there, their surgery is there, their  
:48:55 cadaver labs are all there. They could do it all under one  
:48:58 roof. It was also in a private hospital. It wasn't at a  
:49:02 university where we have a little different constraint  
:49:05 sometimes. I would say, you know, we wished everybody had  
:49:11 that system. And the collegiality and true working together  
:49:18 as a team is what produced it, I think.

:49:24 Q. When you were at ISK in that period, yourself, what  
:49:28 did you observe about the collegiality, the collaboration  
:49:34 and the teamwork among the surgeons who were there,  
:49:38 including Dr. Insall, Dr. Scott and drew Dr. Scuderi?

:49:42 A. I think Mr. Davis said it. During the nineties, Dr.  
:49:48 Scuderi almost always operated on the same patient as Dr.

Callaghan - direct

Insall. He had his own patients, but Dr. Insall's patients, he would actually operate on them.

Dr. Scott would be right in the next room. So I visited there, I would obviously be going back and forth talking to both of them, because they all had different techniques of what they were doing. Everybody doesn't do things exactly the same.

So I talked to one about why he did that and the other guy didn't do that. Then we would get into talking about, you know, aspects of design, that, as I said, I was developing the same type of designs they were during that same period of time.

Q. Let's now go to the actual contributions that were made to the claims by Dr. Scott and Scuderi. That is the subject we are going to go into.

First, based on your experience and based on your review of the materials that you had described before, what is your understanding about whether Dr. Scott and Dr. Scuderi were involved in the initial design ideas for increasing posterior condyles as a way to safely achieve higher degrees of flexion.

MR. HIGER: Your Honor, this is not the subject of expert testimony. This is factual testimony about whether as a matter of fact Dr. Scott and Scuderi were involved in the initial conception as opposed to an overview

Callaghan - direct

:51:26 of the documents that he reviewed to see if there is  
:51:30 sufficient evidence for him to have an opinion of  
:51:33 contribution. For that reason, we object.

:51:37 MR. FRIEDMAN: I think, Your Honor, that we have  
:51:39 an obligation to be able to identify what the contributions  
:51:46 are and to tie the contributions into the claims of the  
:51:52 patent. It's our burden to do those things.

:51:55 THE COURT: There is no disagreement on that.

:51:57 MR. FRIEDMAN: Right.

:51:59 THE COURT: Counsel, you don't disagree with  
:52:05 that.

:52:05 MR. HIGER: Your Honor, we don't disagree, it is  
:52:08 their burden to show contribution to novel elements of the  
:52:12 claim. This witness doesn't have the foundation to be able  
:52:15 to talk about those interactions because he wasn't involved  
:52:17 in them personally.

:52:19 THE COURT: Yes. That's the important  
:52:22 objection.

:52:23 MR. FRIEDMAN: Yes, Your Honor. I think as an  
:52:25 expert witness -- clearly, he is an expert --

:52:28 THE COURT: I guess you are going to get into  
:52:30 some hearsay objections in a moment. Counsel?

:52:32 MR. HIGER: That is entirely possible, Your  
:52:34 Honor.

:52:34 THE COURT: Go ahead.

Callaghan - direct

:52:34 MR. FRIEDMAN: Well, I don't want to anticipate  
:52:37 those objections. But I think, Your Honor, unless you say  
:52:42 expert testimony is not necessary --

:52:46 THE COURT: No. I don't think I am saying that.  
:52:49 Go ahead.

:52:50 MR. FRIEDMAN: I think that we need to be able  
:52:55 to have someone who can look -- an expert who can look at  
:52:59 the contributions, look at the claims and say, yes, I see  
:53:03 these contributions, and as an expert in this subject  
:53:07 matter, I see these contributions reflected in the claims.

:53:11 THE COURT: I think he agrees with you on that.

:53:14 MR. FRIEDMAN: Yes. And as an expert, he is  
:53:19 also entitled to rely upon the things that experts would  
:53:23 ordinarily look at.

:53:24 THE COURT: That's his complaint, that you are  
:53:27 drifting afield from that which you have just articulated.  
:53:30 We all know that are experts rely upon many things. Do you  
:53:35 want to say something else?

:53:36 MR. HIGER: No, Your Honor. I was just standing  
:53:38 up to be respectful to the Court.

:53:41 THE COURT: You don't have to stand while I am  
:53:43 running my mouth.

:53:45 MR. FRIEDMAN: That is why in the predicate to  
:53:47 my question I said based on your review of the materials,  
:53:53 that mountain of materials.

Callaghan - direct

:53:54 THE COURT: He qualified it that way.

:53:56 I am going to let the Doctor respond as the  
:54:01 question is qualified. I am going to ask counsel to restate  
:54:08 the question. I will to listen again more carefully. I  
:54:12 understand your objection. I have it in mind. I will let  
:54:15 you know.

:54:16 BY MR. FRIEDMAN:

:54:16 Q. Let me restate the question.

:54:18 Based upon your experience as a developer  
:54:23 surgeon, all that other experience you talked about, and  
:54:26 based upon the materials that you reviewed in this case,  
:54:31 what is your understanding of whether Dr. Scott and Dr.  
:54:34 Scuderi were involved in the initial design ideas relating  
:54:40 to increasing posterior condyles as a way to increase  
:54:45 flexion?

:54:46 MR. HIGER: Your Honor, he has repackaged the  
:54:50 question a little bit, but he is focusing on the initial  
:54:53 design ideas instead of a review of the entirety of the  
:54:56 record.

:54:57 THE COURT: I think he said based on the  
:54:58 materials. He didn't say the entirety of the materials.

:55:02 MR. HIGER: The objection is with the initial,  
:55:04 because this witness wasn't at those design and development  
:55:07 meetings. Dr. Scuderi just said, these were oral  
:55:10 discussions.

Callaghan - direct

:55:11 THE COURT: I could have Mr. Maurer read it  
:55:13 back.

:55:15 Do you understand? Just don't use that word.

:55:18 I think he is asking an appropriate question. I  
:55:20 understand that the doctor, we can't inject the Doctor into  
:55:28 the meetings, he wasn't there, and testify as to what he  
:55:32 surmises was going on. But he can give an opinion based  
:55:36 upon his review of the overall materials, can't he?

:55:40 MR. HIGER: Yes, he can, Your Honor.

:55:42 THE COURT: With that in mind...

:55:43 MR. FRIEDMAN: That is precisely what I am  
:55:45 trying to get at.

:55:45 THE COURT: Okay.

:55:47 BY MR. FRIEDMAN:

:55:50 Q. Let me repeat it again.

:55:53 A. Okay.

:55:54 Q. To be clear.

:55:55 THE COURT: Lawyers and judges do this. I don't  
:55:57 know about Doctors.

:55:58 THE WITNESS: All the time. We are not always  
:56:07 laughing like you guys. You guys do a good job.

:56:10 BY MR. FRIEDMAN:

:56:10 Q. Based on your experience and your review of these  
:56:13 materials that you were describing before which you  
:56:16 reviewed, what is your understanding about whether Dr. Scott



Callaghan - direct

:56:19 and Dr. Scuderi contributed to the designs increasing the  
:56:26 posterior condyles as a way to safely achieve higher degrees  
:56:31 of flexion?

:56:32 A. From reviewing all the material that I reviewed, and  
:56:38 from understanding this whole process, which I just outlined  
:56:44 for the Judge, that Drs. Scott and Scuderi did contribute to  
:56:51 development of the concept of posterior condylar thickening.

:56:58 Q. Did you form an opinion, based on your experience and  
:57:02 review of those materials, as to whether they also  
:57:09 contributed to what has been described as creation of a  
:57:13 fourth compartment?

:57:15 A. They did. Once again, from the review of the  
:57:21 material, that would include deposition testimony and all  
:57:25 the other material we talked about, that they did, indeed,  
:57:28 contribute to the design of the fourth, so-called, fourth  
:57:33 compartment or the super condylar.

:57:37 Q. Same question, just to be clear, based on your  
:57:40 experience and review of the materials, do you have a  
:57:42 conclusion as to whether Dr. Scott and Scuderi contributed  
:57:47 to designing a smooth articular surface to the femoral  
:57:51 component as a way to achieve higher flexion?

:57:54 A. I do. And once again, I think they contributed to  
:57:57 that concept, too, of having that smooth transition that you  
:58:00 talk about.

:58:01 Q. All right. Now, are there specific materials that you

Callaghan - direct

:58:06 can identify you considered in reaching the conclusions that  
:58:10 you just articulated?

:58:13 A. Yes, there are a number of those. Just off the top,  
:58:20 we talked about the May 1 diagram, obviously, sketch. Dr.  
:58:28 Scuderi's testimony about what happened before that. And I  
:58:31 think I can provide a little bit of realization to that.

:58:35 You don't just sit down in your office and draw  
:58:38 something like that out without either thinking about it for  
:58:42 a long period of time rather than on that day, or, you know,  
:58:46 that concept --

:58:48 THE COURT: Doctor, we are coming near the end.  
:58:50 He is interested in the materials that you reviewed. You  
:58:53 will get a chance to talk about that, I am sure.

:58:56 THE WITNESS: Okay. I am sorry. So it was that  
:59:00 deposition, that May 1st diagram that we have already looked  
:59:05 at, a 46may 15th design discussion that I also think is in  
:59:11 the documents, were the three.

:59:13 MR. FRIEDMAN: I am going to want to get into  
:59:15 some of these documents.

:59:16 THE COURT: I think it would be a good time now  
:59:18 that you are going to be getting into those documents.  
:59:21 Let's take our evening break and resume at 9:00.

:59:24 I wold like to see counsel as sidebar on record.

:59:27 (The following took place at sidebar.)

:01:07 THE COURT: First on the record, then I want to

Callaghan - direct

:01:09 go off the record again, revisit what we were talking about  
:01:12 earlier, the subject of settlement.

:01:15 When Dr. Scuderi was testifying about his  
:01:18 background, and he revealed that he had graduated from  
:01:21 Downstate in New York, a light clicked on. So I refreshed  
:01:31 my recollection as to when it was that a very, very, very  
:01:37 close friend of mine graduated from Downstate. And he  
:01:40 graduated three years ahead of Dr. Scuderi. His name is Dr.  
:01:46 Kirk Williams, he is a physician in Phoenix, Arizona. At  
:01:50 one of the breaks I asked Dr. Scuderi if he knew Kirk, and  
:01:54 he said, sure do. Small world.

:01:55 I wanted to go on the record and let you know  
:01:57 that. I have not talked to Kirk about this matter, have no  
:02:01 intention of talking to him about this matter. Will likely  
:02:04 not talk to him at all during this particular period. But  
:02:09 thought it important to let both parties know that. It is a  
:02:16 small world, you know.

:02:19 MR. FRIEDMAN: There is no issue.

:02:21 THE COURT: Let's go off the record.

:02:22 (Discussion off the record.

:06:07 (Court adjourned at 5:07 p.m.)  
:06:11

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Reporter: Kevin Maurer